A Framework for Action:

A Coordinated and Integrated Organ and Tissue Donation and Transplant System for Alberta

The Report of the Alberta Advisory Committee on Organ and Tissue Donation and Transplantation

April 19th, 2000

A Framework for Action

A Coordinated and Comprehensive Organ and Tissue Donation and Transplant System for Alberta

Table of Contents

Executive Summary iii

Glossary of Terms vi

The Alberta Advisory Committee on Organ and Tissue Donation and Transplantation 1

- Committee Membership 1
- Link with National Initiatives 1
- Relationship to the Alberta Health and Wellness Business Plan 2
- Parameters and Format of the Report 3

Methodology 3

- Completing the Work of the Committee 3

A Profile: Organ and Tissue Donation and Transplantation in Alberta 4

- Solid Organ Transplantation 4
- Organ Transplant Activities – Alberta 1999 4
- Waiting for Transplantation 5
- Kidney Failure and Dialysis 5
- Chronic Renal Failure Patients – Alberta, December 1997 5
- Tissue Transplantation 6
- Donation of Organs and Tissues 6
- Donation Activities – Alberta 1999 7

Principles 7

Core Elements of a Coordinated and Comprehensive System 8

The Framework of a New System 11

- General Recommendations 11

Clinical Subcommittee Recommendations 16

Recommendations Related to Donation of Organs and Tissues 16

Recommendations Related to the Living Donation of Organs and Tissues 19

Recommendations Related to Tissue Transplantation and Tissue Banking 22

Recommendations Related to Transplantation 23

Administrative Subcommittee Recommendations 25

Recommendations Related to Policies, Standards and Guidelines 25

Recommendations Related to Monitoring, Evaluation and Reporting 29

Recommendations Related to Public and Professional Education 31

Recommendations Related to Information Systems and Technology 34

Who Will Benefit? 37

Cost Implications 40

Appendix One:

Terms of Reference for the Alberta Advisory Committee on Organ and Tissue Donation and Transplantation A-1

Appendix Two:

Members – Alberta Advisory Committee on Organ and Tissue Donation and Transplantation A-4

Expert Advisors and Contributors A-5

Appendix Three: List of Separate Subcommittee Reports A-6

Appendix Four: Proposed Terms of Reference – Donation and Transplant Governing Committee (DTGC) A-7

Appendix Five: Proposed Terms of Reference – Clinical and Technical Advisory Committees A-9

Appendix Six: Principles for Donation and Transplantation in Canada A-12

A Framework for Action

A Coordinated and Comprehensive Organ and Tissue Donation and Transplant System for Alberta

Executive Summary

This is the final report of the Alberta Advisory Committee on Organ and Tissue Donation and Transplantation (AACOTDT). The Honorable Halvar Jonson, Minister of Health and Wellness, established the AACOTDT in April 1999 and appointed, Heather Forsyth, M.L.A., Calgary Fish Creek as chair.

Purpose of the Alberta Advisory Committee on Organ and Tissue Donation and Transplantation

The mission of the AACOTDT is the development of a framework for a coordinated and comprehensive provincial system of organ and tissue donation and transplantation.

The shortage of organs and tissues for transplantation has been a long-standing issue in Alberta and Canada. In December 1999, 99 Albertans were waiting for a heart, lung, or liver transplant. Throughout 1999, 22 individuals died while waiting for an organ to become available. The number of individuals requiring dialysis increases at a compound annual rate of 7%; during the period of 1997 to 2003, it is expected that an *additional* 500 individuals will require dialysis. For individuals with end-stage kidney failure, transplantation rather than dialysis is the preferred treatment option. Transplantation is also approximately 40% the cost of dialysis in the year following the transplant surgery and for the life of the kidney graft. The need to optimize donation of organs and tissues is significant in order to address the very real health needs of individuals with clinical conditions that warrant the transplantation of organs or tissues. Addressing this need was part of the mission of the AACOTD.

All the recommendations contained in this report were unanimously supported by the AACOTDT membership, a committee comprised of individuals with expertise, experience or special interest in the area of organ and tissue donation and transplantation.

Link with National Initiatives and the Alberta Health and Wellness Business Plan

The strategies and recommendations contained in this report support and complement the work of the National Coordinating Committee for Organ and Tissue Donation and Transplantation (NCC). The NCC was established by the Federal, Provincial and Territorial Ministers of Health to develop an implementation plan for a proposed 13-point strategy to increase organ donation. The NCC completed its final report in November 1999 for the Advisory Committee on Health Services (ACHS). The AACOTDT is well represented at the NCC; members who sit on the NCC have been instrumental in sharing ideas at the provincial level that have been raised nationally, and vice versa. This collaboration has maximized the breadth and quality of discussion about organ and tissue donation and transplantation at both a provincial and national level. It has also ensured that Alberta is well positioned to implement the recommendations flowing from both the AACOTDT and the NCC.

While making recommendations, the AACOTDT drew from the content of the Alberta Health and Wellness Business Plan. The recommendations contained in this report support the values, principles, and four basic goals and pursuant objectives that are contained in the 2000-2001 to 2002-2003 Alberta Health and Wellness Business Plan.

Guiding Principles

During its tenure, the AACOTDT identified several key beliefs that together combine to form a set of guiding principles for a comprehensive and coordinated system of organ and tissue donation and transplantation for Alberta.

1. The overarching goal of organ and tissue transplantation is the improvement of individual and population health.
2. Transplantation positively impacts the quality of life of organ or tissue recipients.
3. The care of organ and tissue donors is a basic health service.
4. Transplant services must be based on the principle of meeting the health needs of Albertans.
5. Consent for donation of organs and tissues must be informed and non-coercive.
6. Every reasonable effort should be expended to honor the known wishes of the deceased with respect to his or her desire to be an organ or tissue donor.
7. Donation of organs and tissues is a gift; organs and tissues are not for sale.
8. The health of a living donor is of paramount importance.
9. The health of the intended recipient must not be compromised as a result of disease transmission from the donated organ or tissue.
10. Evaluation and listing processes must work judiciously and transparently.

Key Recommendations

The AACOTDT has formulated 99 recommendations designed to address and improve a provincial system for organ and tissue donation and transplantation, clarify important ethical issues, and offer a legislative framework to facilitate implementation of a coordinated and comprehensive system of service delivery. Key recommendations include the following:

- A governing committee, supported by three advisory committees, reporting to the Minister of Health and Wellness, will oversee the implementation and management of a provincial organ and tissue donation and transplant system.
- New comprehensive legislation will be developed to serve as the legal foundation for donation and transplantation in Alberta and to replace the *Human Tissue Gift Act*.
- Designated donation and transplant services will be expanded to five other centres outside of Edmonton and Calgary.
- Provincial policies, standards and guidelines will be developed to provide a consistent approach to service delivery, recognizing efficiencies and principles of best practice.
- The province will participate in the development, implementation, monitoring and enforcement of national safety standards for organ and tissue donation and transplantation.
- A province-wide coordinated approach to public and professional education will be developed.
- Critical care services in health regions throughout Alberta will be designated to provide support in the identification and care of organ donors. The coordination and management of an organ donor will rest with a critical care specialist.

- Bereavement support services will be available in all facilities designated to manage and support organ donors because the active participation of the public is critical to donation outcomes.

- Living organ and tissue donation will be enhanced to optimize transplant opportunities, while ensuring the donor is provided care independent from the proposed recipient's medical team. Policies will be developed to guard against coercion, to protect the health of the living donor and to ensure the potential donor is able to comprehend the risks and benefits necessary to make an informed decision.

- The Comprehensive Tissue Centre will be renamed the Alberta Comprehensive Tissue Centre (ACTC) and will be reconstituted to support a province wide network of tissue donation, banking and transplantation within Edmonton, Calgary and designated centres. The ACTC will also collaborate with the Lion's Eye Bank in Southern Alberta.

- Transplant centers will participate in the development of national standards for listing recipients for transplant and developing sharing algorithms, based on scientific principles of best clinical practice and ethical principles of fairness and equity.

- The governing committee will develop a comprehensive accountability framework for monitoring, evaluating and reporting donation and transplant outcomes and compliance with the standards and guidelines.

- An information system will be implemented to facilitate national access to real time information for patients waiting transplantation and to facilitate the matching of organs with appropriate recipients, with the appropriate safeguards to protect the privacy of individually identifiable health information.

Proposed Budget Requirements

It is anticipated that an implementation or working group will establish the final budget details following acceptance of the recommendations contained in this report. However, efforts completed to date suggest that the incremental budget requirements will be as follows:

Implementation and Transition Year	$1.846 M
Year Two	$6.674 M
Year Three	$0.426 M
Total Incremental Impact over three years	**$8.946 M**

Glossary of Terms

Alberta Advisory Committee on Organ and Tissue Donation and Transplantation

Terms Used in Report	The following are the definition of some key terms employed throughout this report of the Alberta Advisory Committee on Organ and Tissue Donation and Transplantation.
Brain Death	The irreversible loss of the capacity for consciousness combined with the irreversible loss of all brain stem functions including the capacity to breathe. Brain death is equivalent to death of the individual, even though the heart continues to beat and spinal cord functions may persist.
Potential Donor	Any person diagnosed as brain dead, by means of clinical examination, following the elimination of any medical contraindications to donation, i.e. conditions representing a potential risk for recipients.
Organ Donor	A potential donor from whom at least one solid organ has been surgically removed and transplanted.
Tissue Donor	A donor from whom tissues have been surgically removed for transplantation. Organ donors may also be tissue donors. Deceased individuals may become tissue donors up to approximately 24 hours after death.
Transplantation	The procedure, comprising a series of technical steps that need to be followed in a defined order, that enables the organs (or tissues) obtained to be transplanted into a recipient.
Living Donation	The donation of an organ (or tissue) from a living person to another living person for the purposes of transplantation.
Living Related Donation (LRD)	The donation of an organ (or tissue) from a living person to an individual to whom he or she is biologically related.
Living Unrelated Donation (LURD)	The donation of an organ (or tissue) from a living person to a biologically unrelated recipient.
Renal	Refers to kidney.
Tissue	The collection of cells and / or intracellular substances taken from either a living or dead human body. These tissues may be transplanted or implanted as viable cells and substances or otherwise preserved, fixed or altered.
Cadaveric	Reference to a donor who is dead as distinguished from a living donor
Donation Rate Per Million Population (RPMP)	The calculation of a rate based on the number of organ and/or tissue donors per million population of a defined area.
Comprehensive Tissue Centre	A comprehensive tissue centre provides a broad range of services related to the recovery, processing, storage, and distribution of tissue. Most comprehensive tissue centres address tissue requirements for bone, skin, tendons, ligaments, fascia, heart valves, and corneal tissue.
Tissue Bank	Provides procurement and banking services for one or more group of tissues, i.e., Lion's Eye Bank in Southern Alberta.

A Framework for Action

A Coordinated and Comprehensive Organ and Tissue Donation and Transplant System for Alberta

The Alberta Advisory Committee on Organ and Tissue Donation and Transplantation

This is the final report of the Alberta Advisory Committee on Organ and Tissue Donation and Transplantation (AACOTDT). The Honorable Halvar Jonson, Minister of Health and Wellness, established the AACOTDT in April 1999 and appointed as chair, Heather Forsyth, M.L.A., Calgary Fish Creek. The mission of the AACOTDT is the development of a framework for a coordinated and comprehensive provincial system of organ and tissue donation and transplantation. The Terms of Reference for the AACOTDT are contained in Appendix One.

The recommendations contained in this report are designed to expand and improve a provincial system of organ and tissue donation and transplantation, clarify important ethical issues, and offer a legislative framework to facilitate implementation of a coordinated and comprehensive system of service delivery. All the recommendations contained in this report were unanimously supported by the AACOTDT membership.

Committee Membership

The AACOTDT is comprised of individuals with expertise, experience or special interest in the area of organ and tissue donation and transplantation. The work of committee members was complemented by the contribution of other individuals. The names and affiliation of Committee Members and individuals who supported the work of the committee in a number of ways are contained in Appendix Two.

The Alberta Advisory Committee on Organ and Tissue Donation and Transplantation is comprised of individuals highly knowledgeable about organ and tissue donation and transplantation in Alberta. All have worked diligently to help the AACOTDT fulfill its mandate.

Link with National Initiatives

In September 1995, the Federal, Provincial and Territorial Ministers of Health approved a national / provincial strategy to address donation and transplantation issues in Canada. In 1997, the Ministers approved a proposed 13-point strategy and convened a national coordinating committee to develop recommendations for implementation. The final report of the National Coordinating Committee for Organ and Tissue Donation and Transplantation (NCC) was delivered to the Advisory Committee on Health Services (ACHS) in November 1999.

The AACOTDT has strived to link its activities with the work of the National Coordinating Committee on Organ and Tissue Donation and Transplantation.

The AACOTDT is well represented at the NCC; members who sit on the NCC have been instrumental in sharing ideas at the provincial level that have been raised nationally, and vice versa. This collaboration has maximized the breadth and quality of discussion about organ and tissue donation and transplantation at both a provincial and national level. It has also ensured that Alberta is well positioned to implement the

recommendations flowing from both the AACOTDT and the NCC.

Relationship to the Alberta Health and Wellness Business Plan

In direct and indirect ways, implementation of the recommendations proposed by the AACOTDT will support the achievement of the following major goals outlined in the Alberta Health and Wellness Business Plan for 2000-2001 to 2002-2003[1]:

Goal 1: To sustain and improve the delivery of accessible, effective, quality health services to Albertans who need them.

Goal 2: To improve the health and well being of Albertans through provincial strategies for protection, promotion and prevention.

Goal 3: To support and promote a system for health.

Goal 4: To optimize the effectiveness of the Ministry.

While making recommendations, the AACOTDT used the Business Plan for the Ministry of Health and Wellness. Indeed, the process adopted by the AACOTDT for developing the recommendations and the direction that these recommendations set, are highly consistent with the values, principles, goals and objectives delineated in the 2000-2001 to 2002-2003 Alberta Health and Wellness Business Plan.

The process utilized to develop the recommendations was the result of collaborative dialogue amongst members of the Committee and the individuals whose names appear in Appendix Two. The recommendations they developed embody the five principles of the Canada Health Act – a system of health care that is accessible, comprehensive in scope, portable, universally available and publicly administered.

Some examples of how the recommendations of the AACOTDT directly embody the values, principles, goals and objectives of the Alberta Health and Wellness Business Plan include those, that, once implemented will:

- Enhance accessibility to donation and transplant services by / through the creation of a network of services in centres throughout Alberta;
- Enhance and / or support the provision of excellence by / through the development and / or use of standards of practice grounded in evidence based findings;
- Enhance and / or support the development of an evaluation framework that identifies accountability for all elements of the system of donation and transplantation;
- Enhance public and professional knowledge about donation and transplantation;
- Enhance the sustainability of the health care system by proposing options that are more efficacious, and in the case of individuals suffering from end stage renal disease, more cost effective than therapies that must be used because of the lack of organs and tissues available for transplantation; and
- Enhance shared decision making amongst users, providers and organizations by / through the establishment of a Donation and Transplant Governing Committee and three permanent Advisory Committee.

[1] Ministry of Health and Wellness Three-Year Business Plan, 2000-2001 to 2002-2003, February 2000.

A careful review of the recommendations contained in the report will reflect significant support for Goals Number 1 and 3 of the current Alberta Health and Wellness Business Plan and indirect support for the objectives and strategies contained in Goals Number 2 and 4.

Parameters and Format of Report

The report consists primarily of recommendations approved by the AACOTDT and the philosophical framework upon which those recommendations were based.

This report consists of 99 recommendations approved by the AACOTDT and the philosophical framework upon which those recommendations are based. A brief overview of donation and transplantation activities in Alberta is also presented.

Additional background information about the recommendations contained in this report appear in different subcommittee reports to the AACOTDT. The titles of subcommittee reports that provide additional details appear in Appendix Three.

This report contains the following:

- An overview of the methodology employed by the AACOTDT to develop its recommendations;
- A profile of organ and tissue donation and transplant activity in Alberta;
- Guiding principles and foundations of a comprehensive and coordinated provincial system of organ and tissue donation and transplantation;
- Committee recommendations; and
- Cost implications.

Methodology

Prior to discussing important issues like system governance and the optimal guiding legislative framework, the AACOTDT struck four clinical subcommittees to identify service related goals and issues.

Completing the Work of the Committee

The AACOTDT struck the following four clinical subcommittees to comprehensively address the complex issues associated with organ and tissue donation and transplantation in Alberta:

- Tissue Donation;
- Living Donation;
- Cadaveric Donation; and
- Transplantation.

The following seven additional administrative subcommittees were struck to address common themes emerging from the clinical subcommittee recommendations:

- Governance and Coordination;
- Monitoring, Evaluation and Reporting;
- Policy, Standards and Guidelines;
- Information Systems/Information Technology;
- Financial Implications and Budget;
- Legislation; and
- Professional and Public Education.

Each subcommittee was asked to identify issues and formulate recommendations to improve organ and tissue donation and transplantation in Alberta. Reports for each subcommittee were reviewed, discussed and approved by the AACOTDT. The combined recommendations of the subcommittees comprise the framework for action to create a comprehensive and coordinated system of organ and tissue donation and transplantation in Alberta.

A Profile: Organ and Tissue Donation and Transplantation in Alberta

Alberta is a leader in the area of transplantation. The province can boast excellence in outcomes related to the transplantation of perfusable organs. Its approach to comprehensive tissue banking is a model for the nation. Work in islet cell transplantation is cutting edge and attracting the attention of the world. The province is limited only by the lack of organs and tissues available for transplantation.

Solid Organ Transplantation

Calgary

Programs for kidney and pancreas transplantation exist in Calgary. Calgary also provides pre and post-operative (long term support) for heart, lung and liver transplant recipients.

Edmonton

Programs for heart, heart/lung, lung, kidney, liver and pancreas transplantation exist in Edmonton. Clinical trials in pancreatic islet transplantation are underway and show good promise for treatment of insulin dependent diabetics.

Organ Transplant Activities – Alberta 1999

Transplants	Edmonton	Calgary	Total
Heart	29	-	29
[illegible]	[illegible]	[illegible]	[illegible]
Double Lung	11	-	11
[illegible]	[illegible]	[illegible]	[illegible]
Kidneys (LRD)[2]	24	18	42
[illegible]	[illegible]	[illegible]	[illegible]
Kidney/Pancreas	5	12	17
[illegible]	[illegible]	[illegible]	[illegible]
Liver (Cadaveric)	67	-	67
[illegible]	[illegible]	[illegible]	[illegible]
Pancreatic Islet[4]	7	-	7
Totals	188	80	268

[2] Living Related Donor
[3] Living Unrelated Donor
[4] For every pancreatic islet cell transplant, two pancreati are required.

- Governance and Coordination;
- Monitoring, Evaluation and Reporting;
- Policy, Standards and Guidelines;
- Information Systems/Information Technology;
- Financial Implications and Budget;
- Legislation; and
- Professional and Public Education

Each subcommittee was asked to identify issues and formulate recommendations to improve organ and tissue donation and transplantation in Alberta. Reports for each subcommittee were reviewed, discussed and approved by the AACOTDT. The combined recommendations of the subcommittees comprise the framework for action to create a comprehensive and coordinated system of organ and tissue donation and transplantation in Alberta.

A Profile: Organ and Tissue Donation and Transplantation in Alberta

Alberta is a leader in the area of transplantation. The province can boast excellence in outcomes related to the transplantation of perfusable organs. Its approach to comprehensive tissue banking is a model for the nation. Work in islet cell transplantation is cutting edge and attracting the attention of the world. The province is limited only by the lack of organs and tissues available for transplantation.

Solid Organ Transplantation

Calgary

Programs for kidney and pancreas transplantation exist in Calgary. Calgary also provides pre and post-operative (long term support) for heart, lung and liver transplant recipients

Edmonton

Programs for heart, heart/lung, lung, kidney, liver and pancreas transplantation exist in Edmonton. Clinical trials in pancreatic islet transplantation are underway and show good promise for treatment of insulin dependent diabetics

Organ Transplant Activities – Alberta 1999

Transplants	Edmonton	Calgary	Total
Heart	29	-	29
Single Lung	**3**	-	**3**
Double Lung	11	-	11
Kidneys Cadaveric	**34**	**43**	77
Kidneys (LRD)	24	18	42
Kidneys (LURD)[3]	**6**	**6**	12
Kidney/Pancreas	5	12	17
Pancreas	-	**1**	1
Liver (Cadaveric)	67		67
Liver (LRD)	**2**	-	2
Pancreatic Islet[4]	7	-	7
Totals	**188**	**80**	**268**

[2] Living Related Donor

[3] Living Unrelated Donor

[4] For every pancreatic islet cell transplant, two pancreati are required

Waiting for Transplantation

A total of 22 individuals died while awaiting a heart, liver or lung transplant in 1999[5]. At the end of December 1999, 99 individuals were awaiting heart, lung or liver transplantation.[6]

Twenty-two individuals died while awaiting a heart, heart/lung, lung or liver transplant in 1999.

Organ	Awaiting Transplantation
Heart	27
Heart/Lung	**4**
Lungs	49
Lung/Liver	**1**
Liver	18
Totals	**99**

Kidney Failure and Dialysis

Kidney transplantation is the preferred treatment option for many individuals suffering from end-stage renal failure. Dialysis is the clinical means by which patients with renal failure are kept alive. However, dialysis does not totally replace all the functions of the kidney. Clearly, the best option for the replacement of kidney function is through a transplant.

Effective December 31, 1997, 926 Albertans were alive with a functioning kidney transplant. A total of 1,031 were receiving some form of dialysis as kidney replacement therapy for their end stage kidney disease.[7] The majority of patients on dialysis hope for a kidney transplant.

The following table presents information on the number of individuals undergoing some mode of dialysis effective December 31, 1997.[8]

The Canadian Organ Replacement Register reports that for Canada, from 1981 to 1997, the absolute number of new dialysis patients has increased at a compound annual rate of 7%.[9]

Chronic Renal Failure Patients – Alberta December 1997

Dialysis Modality	Total
Hemodialysis	666
Peritoneal Dialysis	**365**
Totals	**1031**

[5] Source: HOPE Program, Northern Alberta

[6] *Ibid*

[7] Source: Canadian Organ Replacement Register,Canadian Institute for Health Information, 1999, Table 8 - Summary of Treatment Parameters for All Patients on December 31, 1997, Canada and the Provinces, at www.cihi.ca/facts/corr99tbl/table8.htm

[8] Source: CORR/CIHI 1999, www.cihi.ca/facts/corrdial.htm

Waiting for Transplantation

A total of 22 individuals died while awaiting a heart, liver or lung transplant in 1999[5]. At the end of December 1999, 99 individuals were awaiting heart, lung or liver transplantation.[6]

Twenty-two individuals died while awaiting a heart, heart/lung, lung or liver transplant in 1999.

Organ	Awaiting Transplantation
Heart	27
Lungs	49
Liver	18
Totals	99

Kidney Failure and Dialysis

Effective December 31, 1997, 926 Albertans were alive with a functioning kidney transplant. A total of 1,031 were receiving some form of dialysis as kidney replacement therapy for their end stage kidney disease.[7] The majority of patients on dialysis hope for a kidney transplant.

Kidney transplantation is the preferred treatment option for many individuals suffering from end-stage renal failure. Dialysis is the clinical means by which patients with renal failure are kept alive. However, dialysis does not totally replace all the functions of the kidney. Clearly, the best option for the replacement of kidney function is through a transplant.

The following table presents information on the number of individuals undergoing some mode of dialysis effective December 31, 1997.[4]

The Canadian Organ Replacement Register reports that for Canada, from 1981 to 1997, the absolute number of new dialysis patients has increased at a compound annual rate of 7%.[8]

Chronic Renal Failure Patients – Alberta December 1997

Dialysis Modality	Total
Hemodialysis	666
Totals	1031

[5] Source: HOPE Program, Northern Alberta.

[6] *Ibid*

[7] Source: Canadian Organ Replacement Register/Canadian Institute for Health Information, 1999, Table 8, "Summary of Treatment Parameters for All Patients on December 31, 1997, Canada and the Provinces." at www.cihi.ca/facts/cor99tbl/table8.htm.

[8] Source: CORR/CIHI 1999, www.cihi.ca/facts/corrdial.htm

The Gift of Sight

One of the most dramatic examples of how tissue transplantation can enhance quality of life is with corneal transplantation; it literally can restore sight to a person who is blind.

Through significant efforts of Alberta clinicians and initiatives like the Comprehensive Tissue Centre, Alberta has the potential to become the leader within Canada for tissue donation and transplantation.

Tissue Transplantation

The transplantation of tissues provides many individuals with significant enhancement in their quality of life. One of the most dramatic examples of the benefits of tissue transplantation is through corneal transplants. The transplantation of a cornea can actually restore sight. Other applications for tissue include the use of skin grafts for burn and trauma patients, bone and bone fragments for orthopedic and reconstructive surgery and heart valves for individuals who require valve replacement surgery. The applications for transplanted tissue are continuing to expand to include tendons and other tissues.

With the possible exception of heart valves and skin, tissue transplantation may not be directly responsible for saving lives. However, it is responsible for significantly increasing the recipient's quality of life by restoring function and reducing pain.

Unfortunately, there are no uniform standards or reporting mechanisms for compilation of statistics related to tissue donation and transplantation within Alberta and Canada. This makes comparison and interpretation of donation and tissue transplantation activity problematic on a regional, provincial and national basis.

Donation of Organs and Tissues

Organs and tissues for transplantation come from two sources: individuals who have died (referred to as cadaveric donors) and living donors.

Cadaveric Donation

The majority of organs and tissues available for transplantation are surgically removed from a donor following his or her death. Consent for the use of the donated organs and tissues is obtained from a family member. The gift is made without compensation or reward; it is the beneficence of the family members that makes it happen.

Living Donation

In selected circumstances, it is possible for a living person to donate organs or tissues, e.g., an individual may live a complete and healthy life after having donated one of their two kidneys to another person. The liver has the remarkable ability to regenerate; parents can donate a lobe of their liver to their child. A lobe of a lung of a living person may also be transplanted into another individual. Bone that is routinely removed during hip replacement surgery can be processed and used for transplantation into other individuals.

Donation Activity – Alberta 1999

Donors	Northern Alberta[9]	Southern Alberta[10]	Totals
Living Kidney Donor	30	24	54
Living Liver Donor	**2**	**--**	**2**
Living Surgical Bone Donor	318	--	318
Cadaveric – Organ Only	**13**	**19**	**32**
Cadaveric – Tissue Only	57	29	86
Cadaveric – Organ and Tissue	**11**	**11**	**22**
Totals	**431**	**83**	**514**

Principles

The AACOTDT carefully reviewed the Alberta Health and Wellness Business Plan. The purpose of that review was to ensure all recommendations proposed by the committee complemented and supported the proposed future direction for Alberta Health and Wellness.

During its tenure, the AACOTDT identified several key beliefs that together combine to form a set of guiding principles for a comprehensive and coordinated system of organ and tissue donation and transplantation for Alberta.

1. The overarching goal of organ and tissue transplantation is the improvement of individual and population health.
2. Transplantation positively impacts the quality of life of organ or tissue recipients.
3. The care of organ and tissue donors is a basic health service.
4. Transplant services must be based on the principle of meeting the health needs of Albertans.
5. Consent for donation of organs and tissues must be informed and non-coercive.
6. Every reasonable effort should be expended to honor the known wishes of the deceased with respect to his or her desire to be an organ or tissue donor.
7. Donation of organs and tissues is a gift; organs and tissues are not for sale.

[9] Source: Northern Alberta HOPE Program with the exception of information on Living Surgical Bone Donation and Cadaveric Tissue Only Donation that were provided by the Comprehensive Tissue Centre, Edmonton.
[10] Source: Southern Alberta HOPE Program.

Donation Activity – Alberta 1999

Donors	Northern Alberta[9]	Southern Alberta[10]	Totals
Living Kidney Donor	30	24	54
[illegible]	[illegible]	[illegible]	[illegible]
Living Surgical Bone Donor	318	--	318
[illegible]	[illegible]	[illegible]	[illegible]
Cadaveric – Tissue Only	57	29	86
[illegible]	[illegible]	[illegible]	[illegible]
Totals	431	83	514

Principles

During its tenure, the AACOTDT identified several key beliefs that together combine to form a set of guiding principles for a comprehensive and coordinated system of organ and tissue donation and transplantation for Alberta.

1. The overarching goal of organ and tissue transplantation is the improvement of individual and population health.
2. Transplantation positively impacts the quality of life of organ or tissue recipients.
3. The care of organ and tissue donors is a basic health service.
4. Transplant services must be based on the principle of meeting the health needs of Albertans.
5. Consent for donation of organs and tissues must be informed and non-coercive.
6. Every reasonable effort should be expended to honor the known wishes of the deceased with respect to his or her desire to be an organ or tissue donor.
7. Donation of organs and tissues is a gift; organs and tissues are not for sale.

The AACOTDT carefully reviewed the Alberta Health and Wellness Business Plan. The purpose of that review was to ensure all recommendations proposed by the committee complemented and supported the proposed future direction for Alberta Health and Wellness.

[9] Source: Northern Alberta HOPE Program with the exception of information on Living Surgical Bone Donation and Cadaveric Tissue Only Donation that were provided by the Comprehensive Tissue Centre, Edmonton.
[10] Source: Southern Alberta HOPE Program.

8. The health of a living donor is of paramount importance.

9. The health of the intended recipient must not be compromised as a result of disease transmission from the donated organ or tissue.

10. Evaluation and listing processes must work judiciously and transparently.

Core Elements of a Coordinated and Comprehensive System

The AACOTDT identified four basic beliefs that collectively serve as the foundation for a coordinated and comprehensive system of organ and tissue donation for Alberta. The recommendations presented in this report are predicated upon these beliefs.

During the course of its deliberations, the AACOTDT identified four basic beliefs that collectively serve as the foundation for a new comprehensive and coordinated provincial system of organ and tissue donation and transplantation.

A Balanced Approach

In developing its recommendations, the Committee remained sensitive to the overall resources available for health services.

The AACOTDT supports accessible and affordable health services for all Albertans – including the provision of organ and tissue donation and transplant services. Committee members believe strongly in the value of transplantation of organs and tissues as therapy for well-defined clinical conditions. The expansion of organ and tissue donation and transplant services should be part of the full range of health services available to all Albertans.

Organ and tissue donation and transplantation should be an integral part of a quality health system that advocates for a healthy public and excellence in the provision of all health services.

The AACOTDT recognizes the complex interrelationships between the provision of health services and the health of citizens in our province. We support a balanced approach that advances the quality of all health services and overall improvement of health of the citizens of Alberta. The prevention of diseases and disorders and enhancement of the health status of the public can reduce the need for transplantation on a per capita basis. The preservation and indeed enhancement in the quality of health services throughout the system ultimately benefits patients who require donated organs and tissues as they access such services before and after transplantation. When the entire health system is healthy, everyone benefits.

Responsible Expenditure of Public Sector Resources

The return on the investment of funds required to implement a coordinated and comprehensive provincial system of organ and tissue donation and transplantation is a responsible expenditure of public sector funds in terms of both health outcome and reduction of expenditures elsewhere in the system.

A common mantra for any committee charged with the responsibility of recommending a new framework for the provision of health services is the need for funding. Indeed, in order to implement a coordinated and comprehensive system of organ and tissue donation and transplantation, new funds are required. However, the return on this investment should be significant for Albertans based on both health outcome and reduced expenditures elsewhere in the health system. For this reason, the investment in improving Alberta's organ and tissue donation and transplantation system represents a responsible expenditure of public sector funds.

Although detailed reviews have not been conducted for Alberta, Canadian studies have demonstrated that considerable cost savings can accrue when kidney transplantation replaces dialysis as the treatment modality for end-stage renal failure.[11] There is no reason to believe that these same savings will not be realized in Alberta.

Transplantation is efficacious and cost effective therapy.

Recent studies[12] suggest the cost of dialysis and transplantation are comparable for the first year following a kidney transplant. The cost-savings after year one and for each subsequent year of a functioning graft are estimated to be $51,406 per year for each transplant recipient. Over a five-year period, this equates to a savings of approximately $ 205,624 per person. It is noteworthy that in addition to being less expensive, transplantation is also the preferred treatment option because it restores all kidney functions.

Accountability for Outcomes

A new provincial system for organ and tissue donation and transplantation also provides a framework for accountability for the success of the program.

The transplant community remains committed to monitoring the outcomes of transplantation of organs and tissues. It is committed to providing responsible, efficacious and cost effective therapy. The recommendations in this report for both the management of donation and transplant services and the emphasis on monitoring and evaluation reinforces this responsibility and accountability. Together, they create a framework of accountability regarding all aspects of the donation and transplant process.

---

[11] Keown, P., (1999) Transplant Proceedings, 31.

[12] P. Keown (1999) Transplant Proceedings (33)

The AACOTDT believes strongly that donation must be based on the principle of a giving a gift.

It is the selfless gift of families and loved ones of a deceased person and the beneficence of the living donor that makes transplantation possible.

The AACOTDT believes that with education and the opportunity to make an informed choice, more individuals will consent to the donation of organs and tissues.

The most important component of the foundation for a coordinated and comprehensive organ and tissue donation and transplant system is the beneficence of donors.

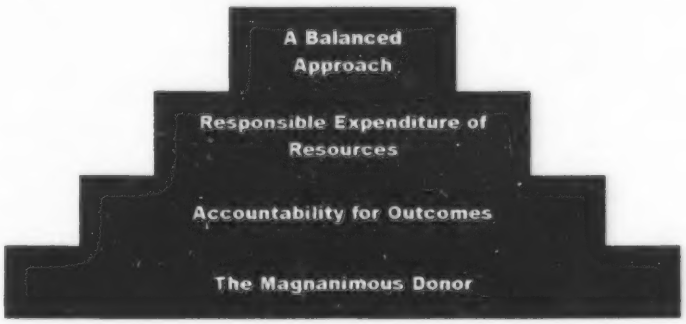
The Magnanimous Donor

The foundation for transplantation is the magnanimous donor. It is the selfless gift of families and loved ones of a deceased person and the beneficence of the living donor that makes transplantation possible.

The AACOTDT are profoundly grateful to the legions of individuals who have consented to donation. Their generosity has extended and improved the life of others during a time when their families or loved ones are often coping with supreme loss.

The AACOTDT believes that with education and the opportunity to make an informed choice, more individuals will consent to the donation of organs and tissues. Many of the recommendations contained in this report are specifically targeted at providing individuals with an opportunity to donate with the objective of increasing the number of organs and tissues available for transplantation.

The Building Blocks for a Coordinated and Comprehensive System for Organ and Tissue Donation and Transplantation



The Framework of A New System

The AACOTDT acknowledged the strengths of organ and tissue donation services that are provided in regions throughout the province. The Committee felt it was important to build upon these strengths to create a strong coordinated provincial system.

A governing body, reporting to the Minister of Health and Wellness, will oversee the implementation and management of a provincial organ and tissue donation and transplant system.

General Recommendations

Together the following recommendations create a framework for a new system of organ and tissue donation and transplantation in Alberta.

Creating a Provincial System

1. Building upon existing strengths in the provision of donation and transplant services, a coordinated and comprehensive provincial system for organ and tissue donation and transplantation should be established.

Governance and Coordination

2. A governing body should be established to govern, lead, and coordinate the implementation and operation of a provincial system for organ and tissue donation and transplantation. Reporting directly to the Minister of Health and Wellness, the Donation and Transplant Governing Committee (DTGC) would be responsible for planning, implementing, funding, making recommendations, managing, and evaluating a provincial approach to the provision of donation and transplant services in Alberta.

   The AACOTDT reviewed the current composition and mandate of the Province Wide Services (PWS) Committee. It felt that a committee analogous to the PWS committee, with a mandate exclusively focused on donation and transplant services, would be an excellent model for overseeing and managing the evolution of a provincial system for donation and transplant services. The AACOTDT favored this approach as it provided a means for overall coordination and funding of activities without legislative change or the need to establish a board analogous to a separate body like a regional health authority. The latter was viewed as particularly important to minimize the infrastructure necessary to support the initiative and the complexity that would be inherent in the effective establishment of another health authority.

   The draft Terms of Reference for the DTGC are contained in Appendix Four.

Three permanent technical advisory committees will provide the Donation and Transplant Governing Committee with expert clinical and technical advice. These committees will be comprised of individuals with expertise and experience in several areas of donation and transplantation. It is envisioned that their expertise will complement the skills of the members of the DTGC.

3. The following three permanent subcommittees to the DTGC should be established to provide expert clinical and technical advise to the DTGC:

   - Donation;
   - Organ Transplantation; and
   - Tissue Transplantation and Tissue Banking.

   The Chairs for each of these permanent Advisory Committees will be appointed by the DTGC and will be members in full standing of the DTGC.

   The establishment of three expert technical advisory bodies to the DTGC was viewed by the AACOTDT as an effective strategy for providing the governing body with input from clinical and technical experts. The three committees also parallel the proposed national structure and will enable Alberta to evaluate and respond in a highly effective manner to both provincial and national issues.

   The Draft Terms of Reference for each of the Technical Advisory Committees are presented in Appendix Five.

The proposed governance and coordination responsibilities of the DTGC are varied and include implementation of the recommendations of the AACOTDT.

One of the first important obligations of the DTGC will be the creation of a business plan that outlines how it will achieve its objectives.

4. The responsibilities of the DTGC should include but not be limited to the following:

   - Serving as a provincial forum for the evaluation, planning, and implementation of an overall provincial framework for organ and tissue donation and transplantation;
   - Developing a business plan that would include:
     - Goals and objectives for a provincial system of donation and transplant services;
     - Strategies for implementing the recommendations of the AACOTDT.
   - Reviewing, assessing and implementing recommendations flowing from national initiatives related to organ and tissue donation and transplantation;

A major responsibility of the DTGC will be the determination of the annual budget for a provincial system of donation and transplantation and the allocation of that budget to regional health authorities that provide the clinical services.

- Developing the budget for the provincial system of donation and transplantation, allocating resources, and monitoring the expenditure of such resources;
- Developing and applying a system of accountability with respect to donation and transplant services in Alberta by / through developing and using provincial, national and international benchmarks and best practices;
- Developing and applying a mechanism to assess new technology (drugs, procedures, and devices) related to donation, transplantation and tissue banking, and providing advice to the Minister of Health and Wellness on the approval and funding of such new technology;
- Monitoring and evaluating practices around adherence and enforcement of safety standards; and
- Producing an annual accountability report on donation and transplantation activities in Alberta for the Minister of Health and Wellness and citizens of Alberta.

The Secretariat

The work of the DTGC and its Advisory Committees will be enabled and facilitated by a permanent secretariat.

5. A permanent Secretariat should be established to facilitate the work of the DTGC and its permanent Advisory Committees.

   The AACOTDT felt that in order to fulfill its mandate and to successfully implement its proposed recommendations, that the DTGC and its Advisory Committees needed the support of a permanent secretariat.

   The need for a secretariat was seen to be essential as the members of both the DTGC and the Advisory Committees would be drawn from amongst individuals who currently work to provide or manage health services for Albertans. Their positions on either the DTGC or the Advisory Committees would be in addition to their other duties and obligations.

Legislative Framework

The AACOTDT concluded unanimously that new legislation was required to serve as the legal foundation for donation and transplantation in Alberta. This view led to the recommendation to replace the existing Alberta Human Tissue Gift Act. Bill 206, championed by the AACOTDT committee chair, MLA Heather Forsyth, underscored the need for a comprehensive and practical legislative framework.

6. An expert panel be convened immediately to develop recommendations for the creation of new legislation to replace the *Alberta Human Tissue Gift Act* with the intent that such legislation would serve as the legal foundation and framework for organ and tissue donation and transplant procedures in Alberta.

   The AACOTDT carefully reviewed the Alberta Human Tissue Gift Act and recommended unanimously that new legislation was required to ensure that Alberta had a sound legal framework to guide donation and transplantation. As part of this analysis, it also considered the development of regulations pursuant to Bill 206, the Human Tissue Donation Procedures Statutes Amendment Act, 1998, that identifies procedures to facilitate donation and transplantation. The committee concluded that the recommendation to replace the Alberta Human Tissue Gift Act obviated the need to proceed with developing regulations pursuant to the Human Tissue Donation Procedures Statutes Amendment Act. Instead, it determined that efforts should be directed towards the creation of new guiding legislation.

A Network of Linked Services

A critical element of the AACOTDT's vision for donation and transplantation in Alberta is the establishment of a linked network of services operating throughout the province. Based on the same guiding principles, these services should be targeted to achieving the goals and objectives contained in the business plan of the DTGC.

7. A coordinated and comprehensive provincial system of organ and tissue donation and transplantation should be predicated upon a network of linked services offered in designated centres throughout the province that share a common business plan and guiding principles.

Implicit in the recommendation for designating centres to provide donation and transplant services is the need to work cooperatively with the management and clinical caregivers within each region. This entails recognizing the unique needs, resources and interests within each region.

The AACOTDT believes that each region will be enthusiastic about trying to improve their ability to meet the health care needs of their residents.

8. The specific types of donation and transplant services to be offered within each designated centre will be predicated upon the following criteria:
   - The need for the designated service(s) within each specific geographic area;
   - The responsible allocation of health resources;
   - The opportunity to cluster similar services to foster the efficient and economic use of human and capital resources;
   - The existing services currently offered within the centre or geographic region;
   - The availability of professionals within the centre or geographic area with expertise in the donation / transplant service;
   - The availability of professionals within the centre or geographic area willing to undertake training to provide one or more of the designated donation / transplant services;

- Access to clinical or technical resources and professionals that provide support to donation / transplantation services;
- Access to facility based resources including but not limited to operating suites, intensive care services, patient care units and outpatient clinics; and
- Access and availability of diagnostic equipment for donor assessment and/or the monitoring of transplant recipients.

The AACOTDT believes that designated donation and transplant related services should be available in the following centres:

- ***Lethbridge***
- ***Medicine Hat***
- ***Red Deer***
- ***Grande Prairie***
- ***Fort McMurray***
- ***Calgary***
- ***Edmonton***

In developing the list of potential services within each designated centre, the AACOTDT did not envision that all designated centres would provide all services. However, a founding belief was that the minimum services to be provided in each designated centre was the identification of organ / tissue donors and intensive care support of the organ donor.

A provincially coordinated approach should dramatically increase the amount of donor bone available for transplantation.

9. The range and type of donation and transplant services identified for designated centres should include some or all of the following:
   - Identification of organ and /or tissue donors;
   - Provision of intensive care support of the organ donor;
   - Informing families about opportunities for organ and / or tissue donation and obtaining consent for donation;
   - Provision of operating room resources for organ and / or tissue retrieval;
   - Provision of technical support for the surgical retrieval of tissue and its transport to the appropriate site for processing;
   - Systems, support and processes for approaching individuals undergoing hip replacement surgery about opportunities for donation of femoral heads and the ensuing next steps in the event the opportunity to donate is accepted;
   - Evaluation of potential transplant recipients;
   - Physical and psychological assessment of potential living donors;
   - Transplant procedures and peri-operative care;
   - Transplant recipient follow-up; and
   - Distribution of immunosuppressive and anti-infective agents.

Decision Making Process

10. Ethical considerations will permeate all decisions related to donation and transplantation including the access and allocation of organs and tissues for transplantation, policy development and implementation, service delivery and follow-up.

Province Wide Toll Free Number

11. A single, province wide toll free number will be established for access by members of the public and health professionals. This toll free number will be used to:

    - Enable health care professionals anywhere in Alberta to gain immediate contact with appropriate parties regarding coordination and support for organ or tissue donation; and

    - Dispense accurate and timely information about organ and tissue donation and transplantation to members of the public and health professionals.

It is anticipated that all regions will participate in programs to educate the public and professionals about indications for organ or tissue donation, transplantation and the benefits of transplantation.

Public Education

12. Programs targeted to the public to enhance awareness of organ and tissue donation and transplantation should be developed as provincial resources with coordinated delivery of these programs at the provincial through to local and community levels. (Refer to pages 31-33.)

More detailed recommendations about public and professional education appear in later sections of this report.

Professional Education

13. Programs targeted to advance education among health professionals about indications and opportunities for organ and / or tissue donation and transplantation should be developed as provincial resources with opportunities for delivery of such educational resources at the provincial, regional, or centre levels or directly to the individual health disciplines. (Refer to pages 31-33.)

Clinical Subcommittee Reports

The donation of organs and tissues is the foundation of transplantation. The gift of an organ or tissue is profound. This gift merits thanks from the citizens of Alberta on behalf of individuals who have been helped by the selfless gift of individuals who are coping with profound loss.

Recommendations Related to Donation of Organs and Tissues

Donor Recognition

14. Donors and their families will be officially recognized for their beneficence.

Role of Health Facilities

All health facilities in Alberta should have a role with respect to organ and tissue donation. The principle role for facilities outside of designated centres relates to professional and public education about indications for donation and transplantation.

15. All health facilities in Alberta will have a role with respect to the donation of organs and / or tissues.

    While it is envisioned that the majority of the organ and tissue donation and transplant activities will occur in designated centres, other facilities will have an important role in educating staff and the public about indications for donation and transplantation. This responsibility extends to caregivers in the community. Individuals who die outside of a hospital environment, for example in a Nursing Home, may be eligible to become tissue donors; health providers have an obligation to try to honor the wishes of the deceased with respect to donation. As a basic principle, all reasonable efforts should be expended to honor the known wishes of the deceased with respect to his or her desire to be an organ or tissue donor.

The establishment of policies within each health facility is regarded as an important strategy for formalizing the role of that facility and educating staff about their responsibilities and obligations.

16. Standard policies will be developed and adopted in all health facilities regarding donation practices. These policies will clearly outline accountability and responsibility for all aspects of organ and tissue donation.

17. Appropriate resources and education will be dedicated to ensure compliance with donation policies.

Critical Care Services in the Support of Organ Donation

The role of critical care specialists, including emergency services, in identifying and supporting organ and tissue donors and their families is extremely important.

18. The mission of critical care services, including emergency services, should include the care of organ and tissue donors. This mission extends to critical care services in hospitals that are not primary transplant centres.

The new provincial framework calls for the designation of intensive care units in centres across Alberta. Caregivers in these centres will possess the expertise to identify and support donors, and provide comfort and support to their families.

19. Critical care services in health regions throughout Alberta that are designated to provide support in the identification and care of organ and tissue donors will have the capacity to admit donors or triage their admission to an alternate critical care service according to specific guidelines set in a provincial triage policy.

20. The common pathway in the management of an organ donor, independent of the venue in which care is provided, will rest with a critical care specialist.

Decoupling Donation and Transplantation Activities

The AACOTDT felt it was imperative to decouple donation and transplant services. Specifically, caregivers involved with the selection of the transplant recipient should not provide care for the organ donor.

21. The function and discipline of coordinating the care of organ donors will be incorporated and fully integrated within critical care services. The function and discipline of coordinating the care of organ donors will not be managed by transplant services.

The AACOTDT recommends that Alberta formally adopt the use of the clinical guidelines regarding the documentation of brain death in adults and children.

Declaration and Documentation of Brain Death

22. The Canadian Neurological Sciences Guidelines for the Diagnosis of Brain Death will be formally adopted in Alberta for the diagnosis and declaration of brain death in adults.

23. Pediatric guidelines for the diagnosis of brain death will be standardized and formally adopted in Alberta.

24. In the absence of national standards for the clinical and diagnostic imaging documentation of brain death, standards for documentation will be developed and adopted throughout Alberta.

Retrieval of Organs and Tissues

25. Organ and tissue retrieval processes should be well planned to minimize delay and disruption.

26. Experienced surgeons trained, where appropriate, in multi-organ retrieval, should lead retrieval teams. Where appropriate, retrieval will be done by surgeons from the donor site.

The provision of bereavement support to families of patients who die is a basic service that should be available regardless of the family's decision about the donation of organs or tissues. The provision of such support should be sensitive to the beliefs and values of different cultures and regions.

Bereavement Support

27. The critical care community has a responsibility for developing and sustaining caring and supportive relationships with the family members of their patients. This responsibility extends to integration of support and follow-up for families whose members have become organ and tissue donors.

28. Culturally sensitive programs that provide support to family members and loved ones of critically ill patients should be implemented and appropriately funded. The culturally sensitive support of loved ones of potential organ and tissue donors should be integrated into these programs.

Activities associated with the maintenance of donors in the intensive care unit and the surgical removal of organs and tissues has traditionally been absorbed by the intensive care units and surgical suites. The cost of providing support of this nature should be funded.

Funding

29. Provincial funding systems will fund clinical donor activities.

30. Through its membership in Inter-Provincial government committees, Alberta will actively lobby for the adoption of funding mechanisms that fairly compensate health facilities for donor management activities that benefit transplant recipients from other provinces.

Philosophical Framework for Donation Practices

31. Alberta will develop position statements regarding a philosophical framework for the foundation of donation practices based on input from several stakeholders including but not limited to clinicians, the public, ethicists, and spiritual leaders.

Recommendations Related to the Living-Donation of Organs and Tissues

Scope of Recommendations

Living donation of organs and tissues relate to the donation of a kidney, or segment of a liver or lung. An opportunity for live donation of femoral heads (bone) also occurs when individuals have hip replacement surgery. This bone is removed as part of the hip replacement surgery and is normally discarded.

Recommendations regarding the donation of tissues, organs or segments of organs from a live donor to a recipient for kidneys, segmental liver, segmental lobes, and femoral heads were considered.

Operating Principles to Govern Living Donation

There is great potential for a living donor to feel coerced or pressured to donate. The donation of organs or tissues from a living donor must be a freely given gift.

Key operating principles are proposed to guard against coercion, insure that the gift of the organ or tissue is informed, and protect the health of the donor and the intended recipient.

32. The following principles shall guide the transplantation of organs and tissues from live donors:

- Donation of organs and / or tissues from a live donor for transplantation is voluntary.
- Means must be established to guard against coercion and to ensure that no coercion has been exercised against a potential donor in reaching a decision regarding the live donation of organs and tissues;
- Consent for donation must be informed and the donor must be competent to make an informed decision;
- Organs and tissues from a live donor are gifts; they must not be sold;
- The safety and health of the potential donor is of paramount importance; and
- The health of the intended recipient should not be compromised by the potential of obtaining a disease from the donated organ or tissue unless justified by disease acuity or severity and with the consent from the patient or next or kin.

There are circumstances where children and dependent adults should be permitted to become organ or tissue donors. However, in each circumstance, the case should be evaluated against pre-existing standards, and be subject to a full ethical review. This is necessary to protect the interests of children and dependent adults.

It is imperative that standards be developed for use at the provincial and national level to guide the use of organs and tissue from live donors who are unable to make an informed decision.

Consent to Living Donation by Children and Dependent Adults

33. In special circumstances, an adult who is generally regarded as being incompetent to make a fully informed decision, or an individual who has not reached the age of consent, (e.g., 16 years) should be permitted to be organ and tissue donors, subject to approved standards and a full ethical review.

34. New legislation should address the need for an independent work up of living donors.

Live donation of a kidney or segment of a lung or liver requires major surgery with some risk to the donor.

Ultimately, the main source of organs for transplantation will result from an increase in the number of cadaveric organ and tissue donors. However, there are circumstances where living donation is in the best interests of all parties. For that reason, strategies should be in place to foster living donation in a manner that is informative and non-coercive.

The Role of Living Donation

35. The donation of organs from a living donor to a recipient should be utilized in circumstances where the donor has an emotional connection to the intended recipient and has altruistic motives. Donation of organs from living donors should be fostered when the potential for receipt of a cadaveric organ is remote and/or the potential of a successful outcome would be significantly compromised by a wait for a cadaveric organ.

36. A proactive approach to increasing the number of living donors should be adopted that includes:

- Extending the pool of potential live donors beyond those who are related to include those who have an emotional relationship with the intended recipient;
- Investing more staff resources to support activities like donor education and counseling, and organizing the work-ups of potential donors;
- Educating health professionals, including primary care providers, about criteria and processes associated with living donation;
- Developing educational resources to complement existing material on live donations;
- Establishing reasonable targets for living donation rates for different transplant procedures.

Donation of Femoral Heads

A normal component of hip replacement surgery is the removal of the femoral head. This tissue is usually discarded after surgery. The femoral head can be processed and subsequently transplanted into individuals requiring different types of orthopedic and bone reconstruction surgery.

37. Within designated centres, strategies should be developed to provide recipients of hip replacement surgery with the opportunity to donate femoral heads that are removed during the surgery. These strategies should include the delineation of roles and responsibilities relative to:

    - Consulting with orthopedic surgeons regarding the implementation and ongoing operation of the program;
    - Consulting with potential hip replacement recipients about the opportunities to donate;
    - Organization of serology screening and lifestyle screening; and
    - Storage and transportation of bone tissue.

Donor Expenses

The reimbursement of expenses should not be construed as payment for the organ or tissue.

38. Live donors should be reasonably reimbursed for expenses associated with being a donor including but not limited to the cost of work-up, travel and living expenses for themselves and a support person, childcare expenses, and other expenses associated with recuperation.

Funding

Funding formulas for donation and transplantation should provide adequate compensation to facilities to underwrite the cost of working up potential donors – several of whom may not proceed to donate because of medical or other issues.

39. Facilities conducting the work-up of potential donors should receive adequate resources to support such activities.

40. Facilities where surgery is performed to remove donor organs should be appropriately compensated for the resources required for surgery and the postoperative recovery of donors.

Funding should also be provided to regions for facility expenses including those associated with the cost of the surgical removal of organs/tissues and post-operative recovery.

41. The expenses associated with the implementation and operation of a program to recover femoral heads from individuals undergoing hip replacement surgery should be funded.

Recommendations Related to Tissue Transplantation and Tissue Banking

Plans for a comprehensive province wide system for tissue procurement, processing and banking is part of the new framework for donation and transplantation in Alberta. It is envisioned that designated centres will play an important role in the procurement of tissues for transplantation. Inventory of banked tissue will be regarded as a provincial resource.

Alberta has one of two comprehensive tissue centres in Canada. It is envisioned that the ACTC will become a centre without walls, and will work to coordinate and integrate all tissue processing, banking and distribution in Alberta. Tissue will be procured within each designated centre and will be processed. The inventory will be regarded as a provincial resource and will be available to all Albertans who require tissue.

It is envisioned that this initiative will result in the increased availability of tissue in inventory in Edmonton, Calgary and other centres where tissue is required for transplantation. It should also reduce Alberta's reliance on imported tissues purchased from tissue banks in the United States.

The National Coordinating Committee, in its final report to the ACHS in November 1999, recommended the establishment of four comprehensive tissue centres in Canada.

Specific roles will be developed for the designated centres relative to the identification of tissue donors and the procurement of tissue.

A Provincial Approach

42. Tissue procurement, processing, storage, and distribution will be established as a comprehensive province wide system that is integrated and coordinated to meet health needs throughout the province.

Alberta Comprehensive Tissue Centre

43. The existing Comprehensive Tissue Centre will be renamed the Alberta Comprehensive Tissue Centre (ACTC) and will be expanded as a provincial resource to coordinate a province wide system of tissue procurement and processing to meet the needs of clinicians and transplant recipients across Alberta. Its responsibilities as a provincial resource will include but not be limited to the following:

- Process and bank tissues, procured within Alberta, at designated centres in Edmonton and Calgary, with the exception of cornea and sclera in Southern Alberta that remain the responsibility of the Lion's Eye Bank;
- Train tissue transplant technicians consistent with international standards and emerging national standards;
- Maintain a provincial inventory of tissues available for transplantation for use by clinicians located at centres across Alberta;
- Ensure that quality and safety standards are maintained;
- Serve as a resource for tissue processing and banking on a cost recovery basis for Western Canada;
- Expand its efforts in basic, clinical and applied research;
- Extend all efforts to become a centre of excellence in tissue processing and banking; and
- Develop a bone processing facility to increase the utilization and permit the maintenance of inventories of bone products throughout Alberta.

The Role of Designated Centres

44. Designated recovery sites for retrieval of tissues will be established in the Lethbridge, Medicine Hat, Red Deer, Fort McMurray, and Grande Prairie. Work in these centres will complement recovery that currently occurs in Edmonton and Calgary.

The indications for tissue donation are different from organ donation. Strategies will be established to identify potential tissue donors who have died within the community, in nursing homes, or other settings. The cooperation of morgue attendants and admitting personnel will be sought in this process.

45. Provincial policies, standards and guidelines will be developed to ensure referral of all potential donors.

Collaboration with Independent Tissue Banks

Cooperation and collaboration with independent philanthropic organizations like the Lion's Eye Bank will be fostered to promote a province wide approach to tissue donation and retrieval.

46. Collaboration and cooperation with the Lion's Eye Bank (Alberta) Society will be fostered.

Inter-Provincial Billing

It is anticipated that the Alberta Comprehensive Tissue Centre in Alberta will become a western Canadian Resource. Processes will be established to seek cost recovery from provinces whose citizens benefit from the services provided by the ACTC.

47. Under the auspices of the DTGC, and with advice from the permanent Advisory Committee on Tissue Transplantation and Banking, rates for services related to tissue processing and banking will be established for any services provided to hospitals outside Alberta.

Scope

Ultimately, it is expected that overall framework for recovering, banking and distributing donated tissue in Alberta will be expanded to include reproductive tissue, cord blood/stem cells, bone marrow and pancreatic islet cells.

48. The feasibility for the recovery, banking and distribution of reproductive tissue, cord blood, stem cells, bone marrow and pancreatic islets should be explored with the intent of integrating these tissue banking efforts into the comprehensive tissue centre framework for Alberta.

    These tissues will require the same level of enforcement of the safety standards as other organs and tissues.

Recommendations Related to Transplantation

Significant aspects about the organization of transplant services, particularly in relation to candidate assessment, recipient follow-up and the distribution of anti-infective and immunosuppressive agents are addressed in the recommendations related to designated centres.

Location of Surgical Transplant Programs

49. The location of surgical transplantation and peri-operative care will be placed in centres of sufficient size to optimize the number of referrals and ensure that the transplanting centre(s) perform a sufficient number of procedures to preserve and enhance the quality of service. The latter will be based on benchmarks established nationally and internationally for the optimal size and volume of transplant services.

Clear and transparent criteria for accepting an individual as a candidate for transplantation, and for allocating scarce organs, is an important element of Alberta's new framework for donation and transplant services. Alberta advocates working closely with its national and provincial partners to improve upon existing strategies for listing patients for transplantation, and to develop new and refine existing algorithms for the allocation of scarce organs.

Listing for Transplantation

50. Alberta will actively participate in the development of national listing criteria with input from the following:

    - Transplantation experts and programs;
    - Specialists in individual organ systems;
    - Public; and
    - Experts in ethics.

Sharing Algorithms

51. Alberta will actively participate in the development of national sharing algorithms for organs and tissues that are predicated upon:

    - Ischemic scope of each organ to achieve the best possible transplantation outcomes;
    - Articulated principles that are consistent with the overarching goal of ensuring fairness and equity in the allocation of scarce organs;
    - Informed discussion and consensus among representatives of the appropriate constituencies, including expert clinicians, ethicists, and members of the public;
    - Open and transparent processes; and
    - Emerging evidence-based findings on transplantation and the evaluation of outcomes of transplant programs nationally and internationally.

Organ transplantation spans provincial borders. For that reason, it is necessary to develop strategies that underwrite the cost of services provided to the citizens of one province on behalf of another.

It is incumbent upon the transplant community to work in concert with Alberta Health and Wellness regarding emerging pharmaceutical technology to ensure that these agents are funded and available for transplant recipients in a timely manner.

Funding

52. Through its membership and participation on inter-provincial coordinating committees and national bodies, Alberta will lobby for a national approach to fund transplant services that provides reasonable compensation for transplantation services provided in Alberta to Canadians who reside outside Alberta.

53. The approval of provincial funding for new immunosuppressive and anti-infective agents for which evidence demonstrates improved therapeutic benefits over existing drug regimens will occur in a timely manner in order to provide the best possible treatment options and outcomes for transplant recipients.

    Processes need to be developed to plan for the release / approval of new pharmaceutical agents that will facilitate their availability and utilization.

Many individuals faced with the physical and emotional burden that accompanies serious illness or injury, including end stage organ failure, may also be burdened by significant financial stress brought about by the inability to work or the need to relocate to another centre while awaiting the transplant procedure and during the post operative recovery period.

54. The Committee recognizes the potential for financial burden for the patient that can accompany catastrophic illness, including transplantation, and therefore recommends that this be reviewed and mitigated where possible.

Administrative Subcommittee Reports

Recommendations Related to Policies, Standards and Guidelines

Development of Provincial and National Instruments

The National Coordinating Committee for Organ and Tissue Donation and Transplantation strongly advocated for national policies, standards and guidelines in key areas.

55. Alberta supports national collaboration to develop and implement policies, standards and guidelines for organ and tissue donation and transplantation.

- Alberta will actively collaborate, and where possible and practical, take a lead role to identify and coordinate the development of policies, standards and guidelines that are required nationally to achieve the recommendations of the National Coordinating Committee for Organ and Tissue Donation and Transplantation;

- Alberta supports the recommendation of the National Coordinating Committee for Organ and Tissue Donation and Transplantation that the Canadian Council of Health Services Accreditation (CCHSA) should evaluate compliance with national policies, standards and guidelines.

The AACOTDT believes Alberta should take a lead role or collaborate actively with its national and provincial partners in the development of policies, standards and guidelines. Among some of the areas where national policies, standards and guidelines would be beneficial are:

- *Indications and listing criteria for organ transplantation;*
- *Sharing algorithms;*
- *Performance/ outcome measures; and*
- *Data definitions and data dictionaries related to donation and transplantation.*

National and provincial efforts regarding the allocation of hearts, lungs and livers have been ongoing. The AACOTDT also identified the need to establish improved protocols for the equitable allocation of corneas for transplantation.

An important consideration in the field of transplantation is equity, fairness and transparency in the allocation of scarce organs and tissues.

The AACOTDT strongly endorses the development or refinement of processes at a national level for the allocation of hearts, lungs and livers. The committee also felt that it would be beneficial to have informed discussion amongst key stakeholders regarding a provincial approach to the allocation of kidneys and tissues.

Enforcement of National Policies, Standards and Guidelines

56. Alberta will participate in the enforcement of national policies, standards and guidelines.

Sharing Algorithms

57. Alberta supports the development of guidelines for the allocation of organs and tissues that reinforces the values of equity, fairness and transparency:

    - The development or refinement and adoption of national sharing algorithms for the allocation of hearts, lungs and livers is advocated;
    - Informed discussion among key stakeholders regarding a provincial approach to the allocation of kidneys is advocated;
    - Informed discussion among key stakeholders regarding sharing algorithms is advocated.

Policies, Standards and Guidelines within the Alberta Framework

58. The DTGC will have ultimate responsibility for ensuring that appropriate policies, standards and guidelines are developed.

59. Policies, standards and guidelines will be developed to guide the following:

    - The management and administration of donation and transplant services in Alberta;
    - The provision of donation and transplant services within the various hospitals and regions;
    - The protection of the confidentiality of private individually identifiable health information;
    - The enforcement of national safety standards for organ and tissue donation;

Ultimately, the DTGC – the governing and leadership body for donation and transplantation in Alberta -- will have responsibility and accountability for determining the types of policies, standards and guidelines that are required.

- The achievement of uniformity at both the provincial and national level in areas including but not limited to:
    - Obtaining and documenting consent;
    - Documents that may be used throughout the region in designated centres including histories, assessment sheets, etc.
    - Declaration of brain death for adults and children and documentation of that clinical finding; and
    - The definitions for important terms, e.g., potential donor.

Standard Operating Procedures (SOPs)

The development and implementation of common policies, standards and guidelines is an important tool for ensuring that donation and transplantation is provincial in scope but locally delivered.

60. Standard operating procedures will be developed for Alberta for each of the core functions associated with donation, transplantation and tissue transplantation and banking that are to be provided within each designated centre:

- SOPs will be created to serve as a resource and tool for all regions who have a designated role in the provision of donation and transplant services;
- All regions providing donation and transplant services will comply with SOPs;
- Education will be provided to the staff of regions with a designated role in the provision of donation and transplant services on how to implement the SOPs;
- A key person will be made responsible within each designated centre for managing and monitoring compliance with the SOPs, and determining where efforts and resources should be directed;

Donation and transplant processes are long and complex. It is envisioned that standard operating procedures (SOPs) will be developed for use within Alberta that provide operational clinical guidelines / standards for donation and transplant services in any of the designated centres.

The creation of SOPs and the use of standardized guidelines are important tools that address the challenges identified in the Alberta Health and Wellness Business Plan. The specific objective is to ensure that Albertans receive the care they need.

- SOPs will be developed in such a manner that regions and hospitals are able to address and respond to local needs while adhering to the overall standards for performance outlined in the SOPs;
- SOPs will be created to facilitate application of the national safety standards and regulations; and
- The DTGC, together with its permanent Advisory Committees, will provide support and guidance to the regions regarding the interpretation and implementation of the SOPs.

61. SOPs will form the basis for evaluating performance in regions relative to their designated role in the provision of donation and transplant services.

Relationship and Reciprocity with Standard Setting and Accrediting Bodies

Currently, there is no accrediting body for comprehensive tissue banks in Canada. The American Association of Tissue Banking (AATB) has accredited the Edmonton Comprehensive Tissue Centre. Similarly, the American Association of Eye Banks has accredited the Southern Alberta Lion's Eye Bank. The AACOTDT believes Canadian standards should meet or exceed the standards of the American accrediting bodies.

62. Alberta will strive to develop standards with respect to the provision of services that permit reciprocal arrangements with important American standard setting bodies.

63. Alberta will actively support the development of a Canadian accrediting body for tissue banking.

64. Alberta will collaborate with its national and provincial partners to develop national standards for donation and transplantation for use by the Canadian Council on Health Services Accreditation.

Review and Update of Policies, Standards and Guidelines

65. Every policy, standard and guideline will be reviewed and updated on an annual basis and more frequently based on emerging developments in evidence based medicine or to ensure compliance with newly approved national policies, standards and guidelines.

66. The DTGC will ensure that an appropriate infrastructure exists to support the development, review, and update of policies, standards and guidelines, with the recognition that this task is one that is complex and potentially resource intensive.

Public Dialogue

67. Public consultation should be sought on new and emerging issues related to organ and tissue donation and transplantation including xeno-transplants and absolute or relative contraindication of age for transplant candidates.

Recommendations Related to Monitoring, Evaluation and Reporting

Monitoring, Evaluation and Reporting within the Alberta Framework

The DTGC has responsibility for creating an accountability framework that enables it to define the scope of its responsibility and the manner in which it is meeting its responsibilities.

68. The DTGC will be accountable for all that falls within its mandate.

Comprehensive Accountability Framework

An essential prerequisite of an accountability framework is the DTGC's annual business plan. The business plan will outline the goals and responsibilities of the DTGC. It will harmonize and support the overall business plan for Alberta Health and Wellness. However, it is necessary to specify the manner in which the DTGC will be publicly accountable for its achievement of the goals and objectives outlined in the business plan. This will be accomplished through a comprehensive strategy for monitoring, evaluation, and reporting.

69. The DTGC, with the involvement of its permanent Advisory Committees and experts in evaluation, will develop a comprehensive accountability framework for monitoring, evaluation and reporting that:

- Outlines roles, responsibilities, and reporting requirements for service providers and management;
- Reflects provincial and national policies, standards and guidelines;
- Is the product of a collaboration among stakeholders;
- Identifies priorities for evaluation on an annual basis;
- Outlines processes to review outcomes, and initiate action for continuous improvement based on demonstrated outcomes;
- Details the data to be reported, by whom and to what bodies;
- Details the timing of reviews to optimize continuous improvement of the system and shared learnings;
- Provides a risk management approach to the provincial strategy for donation and transplantation; and
- Is reviewed and updated on a regular basis to ensure its currency.

Link with the Alberta Health and Wellness Business Plan

70. Goals and objectives for donation and transplantation that are identified within the business plan prepared by the DTGC will support the achievement of goals in the Alberta Health and Wellness Business Plan.

Documents created by the DTGC that outline their responsibilities and processes for measuring and monitoring their achievement should be public documents.

71. The business plan and accountability framework for donation and transplantation in Alberta will be public documents.

National Principles on Organ and Tissue Donation and Transplantation

72. The accountability framework for donation and transplantation in Alberta will be predicated upon the 12 principles identified within the final report of the National Coordinating Committee for Organ and Tissue Donation and Transplantation.

    These principles were approved by the Federal / Provincial / Territorial Ministers of Health in September 1999. They are reproduced in Appendix Six.

Sufficient resources are required to support a dedicated process of monitoring, evaluation, outcomes research and reporting.

Dedication of Resources

73. The DTGC will endeavor to ensure that sufficient resources are dedicated to the process of monitoring, evaluation, outcomes research and reporting.

The adequacy of data definitions related to donation and transplantation is frequently cited as a concern. Alberta will work with its national and provincial partners to improve the adequacy of definitions and to create definitions in key areas where none currently exist.

National Standards for Common Data Definitions

74. Alberta will take the lead role or will work actively with national bodies to review the adequacy of common data definitions for reporting activities related to donation and transplantation to meet the objective of having uniform definitions across Canada. Where there are no existing guidelines, Alberta will take the lead role or work actively with national bodies to create such guidelines.

An important responsibility of the DTGC is to monitor the approval of national standards and ensure that Alberta stakeholders are fully apprised about the content of such standards.

Communication about New and Emerging Standards

75. The DTGC will establish mechanisms:

    - To communicate the content and implications of national standards;
    - Ensure compliance with national standards.

The science of donation and transplantation is rapidly evolving. Indeed, Alberta researchers are working to improve donation and transplant technology. It is incumbent upon the DTGC and its permanent Advisory Committees to monitor improvements relative to donation and transplantation for incorporation within Alberta's system.

76. The DTGC, with advice from its permanent Advisory Committees, will monitor emerging standards and developments in evidence based medicine and clinical research related to donation and transplantation.

Annual Report

77. The DTGC will report on monitoring, evaluation and reporting in its annual report to the Minister of Health and Wellness and the Alberta public.

"What is truly distinctive about transplantation is not technology or costs, but ethics. Transplantation is the only area in all of health care, which cannot exist without the participation of the public. It is the individual citizen who while alive, or in the case of vital organs, after death, makes organs and tissues available for transplantation. If there were no gift of organs and tissues, transplantation would come to a grinding halt."[13]

Recommendations Related to Public and Professional Education

Comprehensive Strategy for Public and Professional Education

78. The DTGC will assign a high priority to the development and implementation of a comprehensive strategy for professional and public education about donation and transplantation.

Professional and public education must be regarded as a continuous strategy and not as an ad hoc, one time only effort.

79. The DTGC will ensure that individuals with expertise in the fields of marketing and education have major input into the development and implementation of a comprehensive professional and public education strategy.

It is absolutely essential that professional and public education programs be differentiated to address the unique and different needs of specific target populations. A one size fits all approach is not advocated.

80. The comprehensive professional and public education strategy will:

- Address key target populations and will be sensitive to key factors including ethnicity, spiritual beliefs and culture;
- Be predicated upon differentiated approaches that are appropriate and meaningful to the target population;
- Address needs within urban and rural centres; and
- Complement and support strategies being developed and implemented at a national level.

The AACOTDT identified several key messages that it believes should be cornerstones of an effective and comprehensive educational strategy.

Messages for Professionals and the Public

81. The comprehensive professional and public education plan will reflect but not be limited to providing information about the following:

- The benefits of organ and tissue donation;
- The benefits of transplantation including outcomes and improved quality of life;
- Criteria for brain death;
- Indications for organ or tissue donation;
- Processes for allocation of scarce organs and tissues; and
- The importance of choosing healthy lifestyles to reduce causes of organ failure.

[13] Arthur Caplan testifying before the US Congress in 1990.

In order to develop effective differentiated professional and public education strategies, it is highly recommended that information about the needs, attitudes and preferred learning methods of each target population be obtained.

Assessing Education Needs

82. Representatives of the target populations to whom educational efforts are being addressed will be consulted regarding:

    - Their needs;
    - Prevalent attitudes about organ and tissue donation and transplantation; and
    - Effective and preferred strategies for being educated about donation and transplantation.

The establishment of partnerships will be an important component of the implementation and operation of a comprehensive professional and public education program. Among the partnerships envisioned are those with the National Donation and Transplant Council; provincial government ministries including Alberta Health and Wellness, Justice and Learning; Regional Health Authorities, community and volunteer groups, and professional and regulatory bodies.

Partnerships and Collaboration in Educational Initiatives

83. The professional and public education strategy will utilize partnerships and collaboration at the national, provincial, regional and local levels to further its educational aims.

84. Government ministries will collaborate to identify and utilize common opportunities to disseminate information about organ and tissue donation and transplantation.

85. The DTGC will ensure that reference material and resources are developed to facilitate professional education of staff in facilities designated to provide donation and transplant services.

Many health professionals lack basic knowledge about indications for organ or tissue donation, transplantation, or transplant outcomes. An important role of the DTGC is to ensure that accurate, relevant information is available to facilitate professional education.

Educational Programs for Health Professionals

86. Educational programs for health care professionals should emphasize:

    - Technical skills related to donation and transplantation;
    - Communication and human relationship skills associated with approaching families about donation, bereavement support, and managing the stress often associated with providing support to families during end of life circumstances.

Many family members struggle with the fact that their loved one has died even though their heart is still beating and a machine continues to ventilate the lungs until the organs are recovered. It is imperative that education programs sensitively and accurately provide information about criteria for brain death.

87. Educational programs for health care professionals should provide detailed support on the content and mode of communication with family members about brain death and the donation process.

Support is required to provide health professionals with guidance regarding interaction with families in crisis and communication about brain death and the donation process.

The AACOTDT recognizes that a critical barrier to donation revolves around the reticence of individuals to discuss end of life decisions and by physicians and other caregivers to raise the issue of donation with family members. It is the lack of comfort around this emotional issue that results in families not having the opportunity to consider donation. It also means that individuals with an acute need for donated organs and tissue do not have the opportunity to have a transplant. Education is required to reduce this reticence and to facilitate health care providers in raising end of life discussions, including opportunities to donate.

Discussion about End of Life Decisions

88. Strategies for initiating discussion about end of life decisions, including opportunities for the donation of organs and tissues, should be an important element of pre-licensure education and of continuing professional education for:

    - Primary care physicians (e.g., family doctors and geriatricians), physicians providing critical care (emergency and intensive care) and other medical specialists;
    - Nurses; and
    - Disciplines including social work, psychology, occupational therapy, pastoral care, and others who routinely provide support and care to families in critical care units and emergency, or who deal with families of deceased both in the community and health care facilities.

It is prudent to consider the emotional and support needs of donor families, transplant recipients and their caregivers and to provide education that addresses those needs. Dealing with the life and death issues surrounding donation and transplantation is emotionally laden; support should be provided to the individuals involved.

Dealing with Emotional Issues

89. Studies should be undertaken to assess the needs of donor families, transplant recipients and caregivers providing support to both groups regarding the education and support that they require to deal with the emotional issues surrounding life and death.

Canada presently does not have a program to train tissue bank technologists; individuals wishing to enter this field must learn on the job or travel to the United States for training. A program that addresses Canadian needs is required.

Training for Tissue Bank Technologists

90. Alberta should take the lead role in developing and offering a program for the training of tissue bank technologists within Canada.

    The National Coordinating Committee is advocating for the establishment of Canadian based training programs for tissue bank technologists. Such a bank would need to be affiliated with a comprehensive tissue centre.

In order to assess whether the public and professional education strategy is achieving its objective, it is important that it be evaluated and modified as required.

Evaluation of Professional and Public Education Programs

91. An evaluation should be conducted on a regular basis of all components of the comprehensive professional and public education strategy.

Recommendations Related to Information Systems and Technology

Comprehensive Information Systems and Technology Strategy

The creation and operation of effective information systems and technology network for donation and transplantation is an important tool for implementing the proposed overall framework for enhancing organ and tissue donation and transplantation.

92. Information systems and technology supporting a coordinated and comprehensive provincial system of organ and tissue donation and transplantation must address a range of requirements including but not limited to:

Real time access to clinical information about a donor and a potential recipient is necessary to facilitate the matching of available organs and tissues with potential transplant recipients. However, this information can be presented in a manner that still preserves the confidentiality of individually identifiable health information.

- Appropriate safeguards to preserve and protect the confidentiality of private individually identifiable health information;
- Appropriate provisions to guard against unauthorized access to information;
- Real time access to donor information to facilitate the exchange of clinical information for the purposes of matching available organs and tissues with transplant recipients;
- Real time access to transplant recipient data to facilitate the equitable allocation of organs and tissues;
- Point of service data collection and retrieval;

The opportunity for donation and transplantation information technology to link effectively with other existing databases, e.g., the Canadian Critical Care Society, is one strategy for minimizing the amount of data that needs to be collected for donation and transplantation.

- Relational and/or linked data bases to minimize and rationalize the number of data elements to be recorded at point of service;

The need for standards for data definitions pertaining to organ and tissue donation and transplantation for use at the provincial and national level is important – particularly in relation to the development of point of service access to online information.

- Development and/or adoption of common data definitions that will be compatible with those employed nationally;

Any information systems and technology that are developed for donation and transplantation must support the aggregation of data at local levels to monitor activities and progress, and research and outcomes analysis to enhance the body of evidence-based knowledge.

- Creation of protocols for the aggregation of data at local, regional and provincial levels to facilitate performance reviews, assessment of outcomes, and any and all other information needs necessary for responsible management and accountability;
- Creation of protocols to support research and outcomes analysis to foster new evidence-based findings regarding donation and transplantation;

Information systems and technology must also support the overall information needs of the Regional Health Authorities and be compatible with the overall blueprint for information technology that has been created through the alberta we//net initiative.

- Compatibility with overall information needs within the Regional Health Authorities;
- Compatibility with the overall blueprint for information systems and technology to support health care in Alberta, specifically the business plan for the alberta we//net initiative.

Specifications for Information Systems and Technology

93. The following strategies and principles should be used to develop and define the specifications for a comprehensive information systems and technology strategy to support a coordinated and comprehensive provincial system for organ and tissue donation and transplantation:

Alberta can learn much about information systems and technology from other jurisdictions that have created software to support clinical, research and management of donation and transplantation.

- A detailed review of existing systems and technology currently supporting organ and tissue donation and transplantation across North America and Europe should be conducted with the intent to learn from, model, purchase and/or otherwise benefit from the experience of others;
- A specific purpose should be defined for all information/data elements collected in order to guard against databases bloated by unnecessary information;
- Alberta should take a lead role and / or collaborate actively with national bodies to develop common data dictionaries and data collection standards;

Strategies must be developed to build upon local information systems that have been successfully used to provide clinical and management support within the various health authorities.

- Local information systems and technology strategies related to organ and tissue donation and transplantation should be respected with the intent that existing successful efforts to capture and review data electronically will be incorporated into the overall provincial strategy; and
- While all components of the system have a responsibility and obligation to adhere to common provincial and national standards for collection and reporting of information, flexibility and autonomy at the local levels should be respected and fostered.

It is envisioned that any information systems and technology developed to support donation and transplantation will be part of the overall strategy for information systems developed by alberta we//net. It is further envisioned that alberta we//net will provide significant technical expertise in defining the necessary system specifications and the plan to create and implement the new information systems for donation and transplantation.

Linking with alberta we//net

94. Support and assistance should be sought from alberta we//net with respect to the:
    - Development of technical specifications for a coordinated and comprehensive information systems and technology strategy for organ and tissue donation and transplantation;
    - Review and evaluation of existing technology and resources with the view for possible adoption of those resources within Alberta;
    - Development of an overall implementation strategy for a coordinated and comprehensive information systems and technology strategy for organ and tissue donation and transplantation; and
    - Actual implementation of the strategy.

While alberta we//net may provide the technical specifications for information systems for donation and transplantation, clinical input is required to determine the type and format of information that is necessary to meet the service and operational aims of the donation and transplant system in Alberta.

95. The DTGC and its permanent Advisory committees will be instrumental in providing and organizing input at the user and expert level regarding the data that should be collected for clinical and management purposes.

    Information systems development will occur once provincial standards and guidelines are developed and specifications for a minimum data set are established.

It is important that the systems that are designed for donation and transplantation operate to reinforce existing program policies.

Reinforcing Program Policies

96. Information systems and technology should be developed in such a manner to reinforce the approved program policies.

Traditionally, data are inputted into electronic databases retrospectively. In order to support key protocols like sharing algorithms, etc., point of service data entry is mandatory. Resources for hardware / software and staff are necessary to facilitate point of service data entry.

Resources for Point of Service Data Entry

97. Resources should be available to support point of service data entry.

Part of the information systems and technology plan should include the provision of information to the public, including indications for organ or tissue donation and transplantation.

Information for the Public

98. The public will be able to access information through various media about donation and transplantation.

Alberta is well positioned to serve as a pilot site for national initiatives in information systems and technology for donation and transplantation. The existence of two large urban centres, several mid sized cities, and large rural areas provide a unique laboratory for testing information systems and technology.

Piloting Information Systems and Technology

99. Alberta should actively endeavor to serve as a pilot site for national initiatives relative to information systems and technology for organ and tissue donation and transplantation.

Who Will Benefit?

It is anticipated that at the end of the three-year implementation period, there will be an annual increase of 24 organ donors and an overall increase in the rate of donation to 25 per million population. The goal of 25 organ donors per million population is consistent with the national goals established in the final report of the NCC to ACHS.

Ultimately, a strong system for donation and transplantation will benefit all Albertans.

At the end of the three-year period of implementation, the volume of services provided to individuals in need will increase. It is anticipated that within three years, there will be an increase of 24 organ donors per year. As a result of this increased rate of donation, it will be possible to increase the annual volume of transplant surgeries in the following manner[14]:

- 12 –14 additional heart transplants;
- 5 – 10 additional lung transplants;
- 18 - 21 additional liver transplants, and;
- 42 - 46 additional kidney transplants.

It is anticipated that transplantation of tissues will increase by approximately 2.5 times the current volume.

These anticipated increases are in addition to existing activity.

It is noteworthy that a total of 22 individuals died in 1999 while awaiting a heart, lung or liver transplant. Most of these individuals died in a hospital intensive care unit. Because of their end stage organ disease, without a transplant, their death was inevitable.

These and all other individuals who die while awaiting a transplant are lost to their family and their friends. With a transplant, they have the opportunity to regain health and once again become productive members of society. In real terms, it may mean that a child benefits from the presence of a parent who would have otherwise died. Society benefits from the contributions that the transplant recipient makes to the community – as productive tax paying members of the workforce through to contributions of a volunteer nature.

[14] Not all organs are used from every organ donor. These anticipated rates are based on historical use of organs from a multi-organ donor within Canada.

The cost-benefits of enhanced organ transplantation are particularly evident with kidney transplantation. Dialysis is available as organ replacement therapy for individuals with end-stage kidney disease. Dialysis is very successful at keeping alive individuals with kidney failure. However, it does not replace all kidney functions; kidney transplantation remains the preferred treatment option. The Canadian Organ Replacement Register estimates that the absolute number of individuals requiring dialysis in Canada is increasing at a compound rate of 7% per year.[15] In 1997, 1031 individuals in Alberta were receiving some mode of dialysis. Using this statistic, during the period of 1997 to 2003, the absolute number of individuals requiring dialysis therapy will increase by approximately 500 individuals.

Canadian studies[16] indicate that dialysis and transplantation cost approximately the same amount for the first year following transplantation. However, in the second and subsequent years, the cost of supporting a person with a kidney transplant is approximately 40% less than dialysis. This represents a total cost savings of approximately $51,400 after year one and in subsequent years of a functioning graft.[17] There is no reason to believe that the experience in Alberta would be substantially different.

It is anticipated that with implementation of the recommendations contained in this report, a range of 42 to 46 additional kidney transplants will be conducted per year by the end of the three-year implementation period. Over a five-year period, this will result in an anticipated cost savings of approximately $9.1 million in reduced health care expenditures compared to renal dialysis ***for the 44 transplant recipients alone.*** The cumulative cost savings for the period of 2003 to 2007 based on the increased volume of 44 kidney transplants per year for each of those years climbs to $22.7million.

Some caution must be exercised in interpreting these cost savings, however, as the critical issue is to reduce the number of patients requiring dialysis on an annual basis. With an increase in the number of new dialysis patients at a compound rate of 7% per year, it is imperative to optimize the donation rate to the maximum level possible to provide transplantation as a treatment option for as many renal failure patients as possible. And, it must be remembered that the pool of kidney donors is not infinite.

---

[15] Source: Canadian Organ Replacement Register/Canadian Institute for Health Information, 1999, Canada and the Provinces www.cihi.ca/facts/corrdial.htm

[16] P. Keown, (1999) *Transplant Proceedings*, 31.

[17] *Ibid.*

There is also a need for ongoing economic studies to determine cost-effectiveness and cost utility, taking into consideration other areas of organ transplantation. Additional information is required about the quality of life for the recipient and the social and economic implications of his or her return to family, work, and the community activities. Studies are also required to understand the implications and impact of new technologies for the pre and post transplant support of patients.

Cost Implications

The following are the initial anticipated ***incremental*** cost implications for implementing the recommendations of the AACOTDT. Funds that are added in the year one will be rolled into the base budget in year two and beyond. In some cases, one time only costs are anticipated. Where this occurs, the one time cost allocation is presented in the effective year (normally the Transitional/Implementation Year) and removed from the budget in the subsequent year, i.e., the figures are not rolled into the base budget. Figures to be removed are bracketed.

Cost Item	Transitional / Implementation Year	Year Two	Year Three
Governing Committee and Permanent Advisory Committees	$102,000	$78,000	--
Major Strategies and Initiatives			
Revisions to Human Tissue Gift Act	$68,000	--	--
Establishment and Operation of Designated Centres in:			
• Fort McMurray			
• Red Deer			
• Grande Prairie			
• Lethbridge			
• Medicine Hat	--	$420,000	$748,000
Comprehensive Tissue Centre (ACTC) Enhancements	$120,000		--
Lion's Eye Bank (Calgary)	--	$60,000	--

Cost Implications

The following are the initial anticipated ***incremental*** cost implications for implementing the recommendations of the AACOTDT. Funds that are added in the year one will be rolled into the base budget in year two and beyond. In some cases, one time only costs are anticipated. Where this occurs, the one time cost allocation is presented in the effective year (normally the Transitional/Implementation Year) and removed from the budget in the subsequent year, i.e., the figures are not rolled into the base budget. Figures to be removed are bracketed

Cost Item	Transitional / Implementation Year	Year Two	Year Three
Provincial Coordination			
Governing Committee and Permanent Advisory Committees	$102,000	$78,000	--
Secretariat and Consulting Support to the Governing Committee and Advisory Committees	**$250,000**	--	--
Major Strategies and Initiatives			
Includes:			
• **Monitoring, Evaluation, and Surveillance**			
• **Implementation and Enforcement of Standards and Guidelines**			
• **Public Education**			
• **Professional Education**	**$260,000**	**$610,000**	**$100,000**
Revisions to Human Tissue Gift Act	$68,000		
Information Systems	**$40,000**	**$3,400,000**	**($2,400,000)**
Establishment and Operation of Designated Centres in:			
• Fort McMurray			
• Red Deer			
• Grande Prairie			
• Lethbridge			
• Medicine Hat	--	$420,000	$748,000
Establishment of Non - Renal Transplant Clinic in Calgary	--	**$100,000**	--
Comprehensive Tissue Centre (ACTC) Enhancements	$120,000		
ACTC - Capital Equipment	**$350,000**	**($350,000)**	
Lion's Eye Bank (Calgary)	--	$60,000	--

Cost Item	Transitional / Implementation Year	Year Two	Year Three
ICU Bereavement Support Program	--	**$300,000**	--
Enhancement – HOPE Coordinators Calgary	$160 000	--	--
Enhanced Donation Activities including Multi-organ Donor Support	**$120,000**	**$520,000**	**$800,000**
Enhanced Transplantation Activities (Organ and Tissues)	$376 000	$1 536 000	$1 178 000
Totals	**$1,846,000**	**$6,674,000**	**$426,000**

Total Incremental Adjustments over Three Years	**$8,946,000**

Cost Item	Transitional / Implementation Year	Year Two	Year Three
Enhancement – HOPE Coordinators Calgary	$160,000	–	–
Enhanced Transplantation Activities (Organ and Tissues)	$376,000	$1,536,000	$1,178,000
Totals	$1,846,000	$6,674,000	$426,000
Total Incremental Adjustments over Three Years			$8,946,000

Appendix One:

Terms of Reference[18]

Alberta Advisory Committee on Organ and Tissue Donation and Transplantation

Purpose of Committee:

Organ and tissue transplantation are important clinical strategies for extending or improving the quality of life for Albertans. The donation of organs and tissues is the foundation upon which transplantation services are built. The Alberta Advisory Committee on Organ and Tissue Donation and Transplantation has been convened to:

- Provide advice to the Minister of Health on organ and tissue donation;
- Provide advice to the Minister of Health on organ and tissue transplantation;
- Provide leadership and direction on strategies for increasing the availability of organs and tissues for transplantation; and
- Provide leadership and direction on strategies for the enhancement of organ and tissue transplantation as safe, effective and efficient interventions for extending or improving the quality of life.

Goals of Committee:

- To develop a management model for organ and tissue donation within Alberta that:
    - Maximizes the efficiency and effectiveness of the organ and tissue donation process, and
    - Identifies the responsibilities and accountabilities of the various participants in the donation process.
- To develop a management model for organ and tissue transplantation within Alberta that:
- Maximizes the efficiency and effectiveness of the organ and tissue transplantation process, and
- Identifies the responsibilities and accountabilities of the various participants in the transplantation process.
- To develop strategies and recommendations to enhance organs and tissues available for transplantation in Alberta;
- To develop directives for review, approval and dissemination by the Minister of Health on matters related to organ and tissue donation and transplantation;
- To develop recommendations on the content of the regulations pursuant to Bill 206, *The Human Tissue Donation Procedures Statutes Amendment Act, 1998.*
    - To review and make recommendations for legislative changes relating to organ and tissue donation and transplantation.

Scope of Advisory Committee – Duties and Responsibilities:

In order to achieve its goals, the Advisory Committee will undertake the following specific duties and responsibilities:

1. To develop recommendations for the management and coordination of organ and tissue donation in Alberta that:
    - Maximizes the donation process within an ethical and legal framework; and
    - Identifies an accountability framework for the organization and donation processes.
2. To develop recommendations for the management and coordination of organ and tissue transplantation in Alberta that addresses the objectives of:
    - Maximizing the transplantation process as a means to extend life and/or improve quality of life; and
    - Identifying an accountability framework for the organization and transplantation processes.

[18] As approved by the Minister of Health, April 1999.

3. To develop a plan for implementing, within Alberta, the strategies contained in the study commissioned by the Deputy Ministers of Health on organ and tissue transplantation and distribution in Canada;
4. To develop recommendations and implementation strategies for addressing issues within Alberta that are identified by the Advisory Committee as potential impediments to organ and tissue donation and transplantation;
5. To collaborate with the National Coordinating Committee to facilitate its task of developing strategies at the national level for enhancing organ and tissue donation and transplantation;
6. To utilize the information and strategies developed by the National Coordinating Committee and other national groups convened to improve organ and tissue donation and transplantation and to incorporate the output of their deliberations, where applicable, in Alberta's comprehensive plan for enhancing organ and tissue donation and transplantation;
7. To assist in the development of the program parameters, evaluation strategies and monitor outcomes of any pilot projects related to organ and tissue donation and transplantation that may be undertaken by Alberta on behalf of the Federal Government or the National Coordinating Committee;
8. To collaborate with other provinces as they strive to develop comprehensive strategies for improving organ and tissue donation and transplantation in their province;
9. To develop, as directed, draft directives on organ and tissue donation and transplantation. These directives would reviewed and approved by the Minister of Health and disseminated provincially;
10. To serve as a forum for discussion by Advisory Committee Members on emerging issues impacting, or with the potential to impact, organ and tissue donation and transplantation in Alberta and to develop strategies for managing these issues;
11. To conduct a detailed review of Bill 206, *The Human Tissue Donation Procedures Statutes Amendment Act*, 1998, and prepare recommendations regarding the content of regulations pursuant to that Act to be utilized by Alberta Justice to formally prepare regulations;
12. To liaise with Alberta Justice regarding the logistics of preparing content guidelines for regulations pursuant to Bill 206;
13. To review and make recommendations for legislative changes relating to organ and tissue donation and transplantation;
14. To complete other duties as may be assigned, by the Minister of Health.

Authority and Reporting Relationships:

The Advisory Committee on the Organ and Tissue Donation and Transplantation was established by the Minister of Health. The Committee reports to the Minister of Health through the Health Strategies Division.

Membership:

1. The Advisory Committee Membership and designated alternates will be drawn from the following:

   Non Government Representatives:
   - Administrator – Calgary Regional Health Authority
   - Administrator – Capital Health Authority
     - Alberta Medical Association
     - Canadian Association For Pastoral Care Practice and Education
     - Comprehensive Tissue Centre
     - Council of Medical Directors of Alberta
     - Council of Medical Officers of Health
   - Critical Care Nurse
   - Donor Family Representative
   - HOPE Program – Southern Alberta
   - HOPE Program – Northern Alberta
   - Kidney Foundation of Canada
   - Member of the Legislative Assembly (Chair)[19]

[19] Author of the Bill 206, *The Human Tissue Donation Procedures Statutes Amendment Act*, 1998.

- Representatives from the College of Physicians and Surgeons of Alberta:
  - Adult Critical Care
  - Emergency Medicine
  - Neuroscience (Neurosurgery or Neurology)
  - Pediatric Critical Care
- Organ or Tissue Transplant Recipient
- Provincial Health Ethics Network
- Transplant Physician – Calgary Regional Health Authority
- Transplant Physician – Capital Health Authority

Government Representatives:

- Alberta Health
  - Denis Ostercamp – Population Health Strategies
  - Prudence Taylor - Population Health Strategies,
- Office of the Chief Medical Examiner
  - Dr. Graeme Dowling

2. Alternates will be named for selected members on the Advisory Committee. It will be incumbent upon each member to communicate with his or her named alternate and to make every effort to ensure that their named alternate attends meetings of the Advisory Committee that they are unable to attend.
3. The Advisory Committee will identify the membership of working groups to the Advisory Committee.

Meeting Frequency:

Meetings will be held four to five times annually or at the call of the Chair. The venues for the meetings will alternate between Edmonton and Calgary.

Expenses:

1. Expenses for travel to meetings may be reimbursed in accordance with government policy.
2. Non-salaried physicians may be paid to attend Advisory Committee meetings in accordance with government policy.

Committee Term:

It is anticipated that the work of the Advisory Committee will be completed by March 30, 2000 at which time it will be disbanded. The Advisory Committee may be disbanded earlier if it has discharged its duties and responsibilities.

Appendix Two

Members – Alberta Advisory Committee on Organ and Tissue Donation and Transplantation

Dr. Azemi Barama	Transplant Surgeon, Calgary Regional Health Authority
Ms. Marilyn Bartoshyk	Critical Care Nurse, Chinook Health Region
Ms. Marie de Borja	HOPE Program – Northern Alberta
Dr. Robert (Bob) Burns	Alberta Medical Association
Ms. Markie Delany	Consumer Representative (Donor)
Dr. Graeme Dowling	Office of the Chief Medical Examiner of Alberta
Dr. Chris Eagle	Administration, Calgary Regional Health Authority
Ms. Yvette Elmquist	HOPE Program – Southern Alberta
Ms. Heather Forsyth	Committee Chair and MLA, Calgary Fish Creek
Mr. Wayne D. Hatt	Consumer Representative (Recipient)
Dr. Ari R. Joffe	College of Physicians and Surgeons of Alberta, Pediatric Critical Care
Dr. Adrian Jones	Council of Medical Directors (to September 1999)
Dr. Norman Kneteman	Transplant Surgeon, Capital Health Authority
Dr. Jonathan Lakey	Comprehensive Tissue Centre, Capital Health Authority, Edmonton
Ms. Michele Lahey	Administration, Capital Health Authority
Mr. Denis Ostercamp	Population Health Strategies, Alberta Health and Wellness
Dr. Kenn C. Petruk	College of Physicians and Surgeons of Alberta, Neurosciences Program
Mr. Neal Roehl	Alberta Region of the Canadian Association of Pastoral Practice and Education
Dr. P. S. Razvi	Council of Medical Directors (from September 1999)
Dr. J. Dean Sandham	College of Physicians and Surgeons of Alberta, Adult Critical Care
Ms. Linda Spencer	The Kidney Foundation of Canada
Dr. Michael Stingl	Provincial Health Ethics Network
Ms. Prudence Taylor	Population Health Strategies, Alberta Health and Wellness
Ms. Kathryn Burke	Burke & Associates Inc., Project Consultant
Ms. Petra Schulz	Burke & Associates Inc., Consulting Associate

Expert Advisors

The following individuals provided contributions in the development of reports of the various subcommittees or participated in AACOTDT Meetings. Their contribution is very much appreciated.

Ms. Karel Bennett	Legislative Services, Alberta Health and Wellness
Dr. Paul Boiteau	Critical Care, Calgary Regional Health Authority
Ms. Pat Breakey	Province Wide Services, Capital Health Authority
Dr. Sandra Cockfield	Division of Nephrology and Immunology, University of Alberta
Dr. Chip Doig	Critical Care, Calgary Regional Health Authority
Mr. Ralph Fernando	Finance, Capital Health Authority
Dr. Noel Gibney	Critical Care, Capital Health Authority
Ms. Kim Kerrone	Province Wide Services, Calgary Regional Health Authority
Ms. Margaret King	alberta we//net
Dr. Richard Lee	Emergency Medicine, Capital Health Authority
Mr. Cec Mackenzie	Chair, The Lions Eye Bank (Alberta) Society
Mr. John McAllister	alberta we//net
Ms. Susan Mumme	Transplant Administration, Capital Health Authority
Ms. Anne Munguia	HOPE Program, Northern Alberta
Dr. Lynn Redfern	Alberta Health and Wellness
Mr. Dennis Stang	Province Wide Services, Alberta Health and Wellness
Dr. James Shapiro	Liver Transplantation, Capital Health Authority
Ms. Gail Stevens-Guille	Neuro-Sciences Administration, Capital Health Authority
Ms. Sheila Wasylyshyn	Calgary Regional Health Authority
Mr. Bill Webber	Past International Director, The Lions Eye Bank (Alberta) Society
Dr. Serdar Yilmaz	Transplant Surgeon, Calgary Regional Health Authority
Ms. Kim Young	Family Support Program, Capital Health Authority

Appendix Three

List of Separate Subcommittee Reports

The following subcommittee reports complement the contents of this report.

Clinical Subcommittees

- Report of the Donation Subcommittee
- Report of the Transplantation Subcommittee
- Report of the Tissue Subcommittee
- Report of the Living Donation Subcommittee

Administrative Subcommittees

- Report of the Governance and Coordination Committee
- Report of the Legislation Subcommittee
- Report of the Monitoring, Evaluation and Reporting Subcommittee
- Report of the Policy, Standards and Guidelines Subcommittee
- Report of the Information Systems/Information Technology Subcommittee
- Report of the Professional and Public Education Subcommittee

The findings of the Financial Implications and Budget Subcommittee is embodied in the AACOTDT final report.

Appendix Four

Proposed Terms of Reference
Donation and Transplant Governing Committee (DTGC)

Purpose

Reporting to the Minister of Health and Wellness, the DTGC will serve as the senior governing and management body for donation and transplantation in Alberta.[20]

Committee Responsibilities

The responsibilities of the DTGC should include but not be limited to the following:

- Serving as a provincial forum for the evaluation, planning, and implementation of an overall provincial framework for organ and tissue donation and transplantation;
- Developing a business plan that would include:
    - Goals and objectives for a provincial system of donation and transplant services;
    - Strategies for implementing the recommendations of the AACOTDT.
- Reviewing, assessing and implementing recommendations flowing from national initiatives related to organ and tissue donation and transplantation;
- Developing the budget for the provincial system of donation and transplantation, allocating resources, and monitoring the expenditure of such resources;
- Developing and applying a system of accountability with respect to donation and transplant services in Alberta by / through developing and using provincial, national and international benchmarks and best practices;
- Developing and applying a mechanism to assess new technology (drugs, procedures, and devices) related to donation, transplantation and tissue banking, and providing advice the Minister of Health and Wellness on the approval and funding of such new technology;
- Monitoring and evaluating practices around adherence and enforcement of safety standards; and
- Producing an annual accountability report on donation and transplantation activities in Alberta for the Minister of Health and Wellness and citizens of Alberta.

Committee Membership

The Minister of Health and Wellness will appoint all members of the DTGC. Membership shall be comprised of the following:

- DTGC Chair;
- Chief Executive Officer (CEO), or a representative of the CEO, from the:

[20] The role of the DTGC is viewed as being analogous to that of the existing Province Wide Services Committee.

- Calgary Regional Health Authority;
- Capital Health Authority; and
- The five (5) health regions with sites that are designated to provide core donation and transplant services through the provincial of donation and transplantation network;

- The Chairs of each of the following permanent Advisory Committees to the DTGC:
  - Donation;
  - Organ Transplantation; and
  - Tissue Banking and Transplantation;
- Two (2) medical directors from the Council of Medical Directors;
- A senior Provincial Government Official with responsibilities equivalent to an Assistant Deputy Minister;
- A representative to provide a link with academic organizations, to be appointed from either the University of Alberta or the University of Calgary;
- Representative of the Alberta Association of Registered Nurses from the area of critical care nursing;
- Representative of the College of Physicians and Surgeons of Alberta;
- Representative of the Alberta Medical Association;
- Representatives of the Public, including a transplant recipient and family member of a donor;
- Ethicist; and
- Head of the Secretariat serving the DTGC in an ex officio capacity.

Accountability

The DTGC will be accountable to the Minister of Health and Wellness.

Appendix Five

Proposed Terms of Reference – Clinical / Technical Advisory Committees

Purpose of Committees

Three permanent advisory committees, with membership appointed by the DTGC, will be created to provide expert clinical and technical advice in the following areas:

- Donation;
- Transplantation; and
- Tissue Banking and Transplantation.

Role and Responsibilities of the Advisory Committees:

- To provide expert advice to the DTGC on the establishment of standards, goals and outcomes.
- To respond to requests from the DTGC to investigate issues and or make recommendations on matters relating to their area of expertise;
- To monitor the effectiveness of safety and practice standards and assess opportunities for change in policy and service delivery;
- To facilitate communication among all stakeholders; and
- To evaluate the provincial strategy to enhance donation and transplantation and to make recommendations to the DTGC on areas of change.

Membership - Donation Advisory Committee

- Chair;
- Regional Director for Critical Care – Calgary;
- Regional Director for Critical Care – Edmonton;
- One (1) intensivist and/or medical representative from **each** health region outside of Edmonton and Calgary that hosts a designated site for the provision of specified donation and transplantation services;
- Ethicist;
- Pastoral Care Representative;
- Donor Coordinator;
- Critical Care Nurse;
- Emergency Nurse;
- Representative of the Office of the Medical Examiner; and

- In an *ex officio* capacity:
    - Head of the DTGC Secretariat, or designate;
    - Chair, or Designate, from the Permanent Advisory Committee on Transplantation;
    - Chair, or Designate, from the Permanent Advisory Committee on Tissue Banking and Transplantation.

Membership – Transplantation Advisory Committee

- Chair;
- Physician Representatives from the following transplant programs:
    - Heart;
    - Lung;
    - Liver; and
    - Kidney (2 representatives)
- Representative from the Non - Renal Transplant Clinic in Calgary;
- Representatives from Administration/Management from:
    - Calgary; and
    - Edmonton
- (2) Transplant Nurses;
- Pharmacist;
- Liaison Nurse from one of the transplant clinics in a designated donation/transplant centre;
- Ethicists;
- In an *ex officio* capacity:
    - Head of the DTGC Secretariat, or designate;
    - Chair, or Designate, from the Permanent Advisory Committee on Donation;
    - Chair, or Designate, from the Permanent Advisory Committee on Tissue Banking and Transplantation.

Membership – Tissue Banking and Transplantation Advisory Committee

- Chair;
- Tissue Banking Scientist;

- Representative Alberta Comprehensive Tissue Centre
- Representative of Lion's Eye Bank – Alberta Society;
- Representative of the Office of the Medical Examiner;
- Two (2) Tissue Transplant Physicians selected from physicians associated with tissue transplantation of Skin, Heart Valves, Bone, Cornea / Sclera.
- Coordinator/technical representative from the Designated Centres outside of Calgary and Edmonton;
- Ethicists;
- In an *ex officio* capacity:
    - Head of the DTGC Secretariat, or designate;
    - Chair, or Designate, from the Permanent Advisory Committee on Donation;
    - Chair, or Designate, from the Permanent Advisory Committee on Transplantation.

Accountability

The Advisory Committees shall be accountable to the DTGC.

Appendix Six

Principles for Donation and Transplantation in Canada[21]

In its report to the Advisory Committee on Health Services on November 30, 1999, the National Coordinating Committee on Organ and Tissue Donation and Transplantation identified some key principles to serve as the foundation for a new system.

Accountability

For public trust, there is a need to understand who is responsible to whom for what. By defining roles and responsibilities for stakeholders, the governments will be accountable to Canadians for the donation and transplant service provided.

Quality

Canadians in need must be assured that the processes employed will optimize donation and transplant outcomes in terms of survival and quality of life, and will meet the highest quality and safety standards. Using a quality management approach, process and outcome standards will be measured to monitor, evaluate and communicate hospital performance.

Evidence Based Decision Making

Sound information is important for improving the quality of decision-making. Evidence was drawn from the scientific literature and analysis of strategies used in benchmark institutions / countries.

Sustainable Outcomes

It is essential that the donation and transplant strategy be sustainable for the future. The system design should ensure optimal donation and transplant practices that will lead to desired outcomes in terms of the availability and quality of services.

Client / Family Centered

The concerns and dignity of clients and their families are paramount. The proposed strategy respects the autonomy, dignity and beneficence of those individuals and families involved in the donation process as well as transplant recipients.

[21] These principles were approved by the Provincial / Territorial / Federal Ministers of Health in September 1999.